ELISA Plate Analyser

User Manual

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1. GENERAL INFORMATION

1.1. Warranty Information

Each Instrument is completely tested and guaranteed for twelve months from delivery The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use and maintenance in compliance with the instructions given in this manual.

Gentaur / GDMS will, at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any travel and man-hour expenses will be charged extra.

In case of tenders warranty would be as per tender terms and conditions.

1.2. Technical Service

Gentaur / GDMS is always accessible to the customers for any kind of information about installation, use, maintenance and others. When asking for service, please refer to this manual and report the data reported on the identification label (serial number).

Only qualified technicians are entitled to repair instruments.
The user should carry out ordinary maintenance.

The technical service of Gentaur / GDMS or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts only, is always available for extraordinary maintenance (repair), under a yearly maintenance contract or on specific demand.

1.3. Contacts

Gentaur / GDMS Belgium
Voortstraat 49
BE – 1910 Kampenhout
Tel: 003222650921
e-mail: account@gentaur.com

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2. GENERAL SAFETY WARNINGS

2.1. Danger – warning symbols

This is a symbol of generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This is a symbol of HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the supply.

This symbol indicates that the instrument makes use of chemical reagents and other dangerous (Corrosive, irritant, or harmful) CHEMICAL SUBSTANCES, which can cause damage to people or materials. When this label is found, pay attention to the manufacturer's recommendations**.**

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not respected.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

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2.1. Use of the Instrument

The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules by qualified personnel.

This manual contains instructions for operation performed by qualified personnel.

A qualified user has to make sure that environmental condition is suitable, the installation is correct, the use and maintenance are proper according to the general safety rules as well as to the particular precautions described in the manual. (However, he is not entitled to repair the instrument).

A qualified technician is entitled to maintain and repair the instrument using the original spare parts according to the given instructions.
Maintain room temperature and humidity as specified in the manual.

If the instrument is not used as described in the manual, the protection provided by the instrument may be impaired.

Alterations to the instrument are prohibited.The user is liable for any improper modification to the instrument, and for the deriving consequences.

Contact the MANUFACTURER service or authorized service center in case the instrument need extraordinary maintenance. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance.

This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.

Warning : This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."

An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

Warning : Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

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3. INTRODUCTION

3.1. Description

ELISA Plate Analyser of Gentaur / GDMS is

user friendly micro plate Analyser. It is compact & lightweight. It is designed to measure and interpret enzyme immunoassay results, both monochromatically and bichromatically. It is intended for in vitro diagnostic use.

3.2. Special Features

The ELISA Plate Analyser can accommodate a flat bottom as well as a round configuration. The carriage is designed in a way that the plate automatically moves smoothly and positions itself accurately in the optical measurement path. Readings are taken continuously.The average value is calculated and results are presented according to the option selected.

The ELISA Plate Analyseroperates on a WIDE voltage (90-270 volt). This eliminates the need for an external voltage stabilizer**.**

The ELISA Plate Analyserhas a special provision, which allows it to be used even when a printer is not available. Readings can be conveniently noted down manually, by using the PAUSE option

The other special features of ELISA Plate Analyserare the following:

- Option of Lamp saving mode.
- Selection of both primary and secondary filters.
- Latest technology with battery back up for 250 tests with QC, more than 2500 result.
- Robust built in 52-column thermal printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- Alphanumeric Patients ID entry.
- Editing of saved tests.
- Human machine user interface: Touch panel, Keypad
- Multi-standard curve up to 12 standard calibrations with one blank optional.
- Access to test by touch of key.
- Capability to connect to 80-column printer for direct report printout.
- Blank is optional.
- Setting of the Date and Time.
- Capable of storing, deleting and recalling tests.
- Multiple calibrator modes.
- Selection of duplicates for both calibrators and samples.

- Extensive software for cut off mode.
- Selection of Positive, Equivocal, Negative cut-off.
- Several pre-programmed calculation modes will help to facilitate data processing of enzyme immunoassays. These are menu driven modes for simple and error free operations.
    - ABSORBANCE MODE
    - CUT-OFF MODE
    - MULTISTANDARD MODE
    - SINGLE CALIBRATOR MODE
    - % ABSORBANCE MODE
    - UPTAKE
    - KINETIC

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3.3. Technical Specification of ELISA PLATE ANALYSER

Human Machine Interface	TOUCH PANEL / KEYPAD
Linear measurement range	0.000 to 3.000 Absorbance Units (A).
Photometric Accuracy	± 2% or 0.007 whichever is higher, from 0 to 1.5 A ± 3% from 1.5 A to 3.0 A
Drift	<0.005 A/hr
Photometric Linearity	2.5 A
Optical measurement	8 Channel
Filters Type of filter Wave Length Half Bandwidth Selection	 Narrow band Interference 405nm, 450nm, 492nm, 560nm, 630nm, & 3 Optional 10nm ± 2nm Automatic by Stepper Motor
Light Source Display Curve Plotting	Tungsten halogen lamp, 20 Watts 6” Graphics LCD, Negative Blue, STN Graphical Representation on Printer
Plate Carrier Movement	Precisely through the stepper motor
Printer Memory	Built in Thermal Printer 52 columns 64 KB Non Volatile RAM Battery backup supporting 125 open channels
Connectivity / RS232 Serial Port/USB	9600 baud, 8 data, 1 stop, no parity bits / USB

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Analysis Mode	Absorbance Cut-off Multi-Standard % Absorbance Difference Uptake Kinetic
Power Wattage Voltage	 75 Watts 115-230 Volt ± 10%, 50/60 hz.
Operation Position	On horizontal flat, rigid and vibration free surface
Operating Conditions Temperature Relative Humidity	 From + 18°C to 35°C Up to 80%
Storage Conditions Temperature Relative Humidity	 From 10°C to 40°C Up to 80%
Enclosure	ABS Fire Retardant
Size (cm)	36 x 36 x 22 (lxbxh)
Weight (Approx)	10 Kgs

4. PACKAGING, TRANSPORT AND STORAGE

4.1. General Warnings

Instrument has to be decontaminated before packing for transportation.

4.2. Packaging

Packaging is needed whenever the instrument is to be transported or shipped by courier or other purposes.

To pack the instrument the following instructions has to be followed:

- Decontaminate the instrument as explained on decontamination chapter of this manual
- Put the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of Safety clearance certificate (copy of Safety clearance certificate is attached at the end of this manual)
- Mark the packaging with address, instrument identification and warning labels

4.3. Instrument Transportation

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of Instrument

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

Relative humidity has to be less than 85%, and temperature between 10ºC and 40ºC.

5. INSTRUMENT DESCRIPTION

5.1. Instrument Working Principle

- Switch on and program the instrument.
- Place the plate firmly onto the carriage.
- Start the test, the plate will be conveyed inside and strip is placed precisely below the optical path. The measurement is carried out step by step.
- At the end of the cycle the results are printed at the same time they are available at the RS232 serial port output.

On starting the test, the plate will be conveyed into the instrument.
Plate is moved in step by step by a well-controlled mechanism and each well is positioned precisely below the optical path. Optical density of each well is measured as explained below.
Based on selected programming mode, sophisticated algorithms are used for analyzing the measured value and presenting the same on the printer, display & RS232 serial port for computer Interface.

The following diagram represents the main functional elements of the instrument:
White light produced by the lamps is focused into a beam by the lens and passes through the sample. Part of the light is absorbed by the sample and the remaining light is transmitted. It is filtered by interference filters and focused onto the photodiodes. The photodiode converts the received light into an electrical signal which is transformed into a digital form, from which the microprocessor calculates the absorbance, taking in account of the blank and bichromatic selection.

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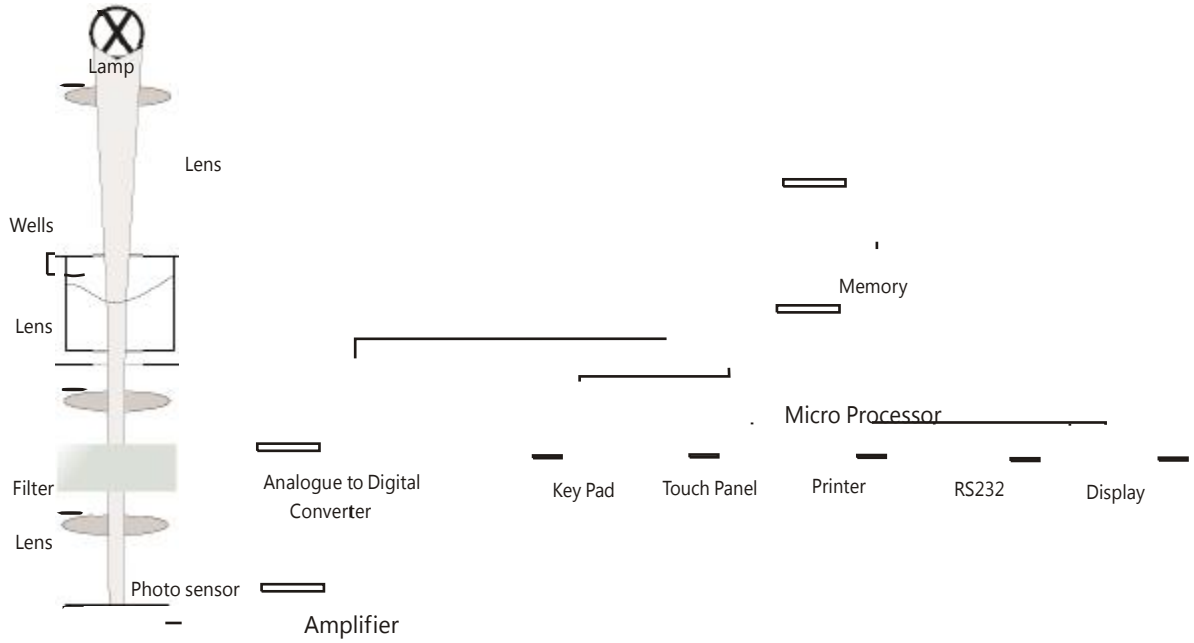
5.2.Perspective View



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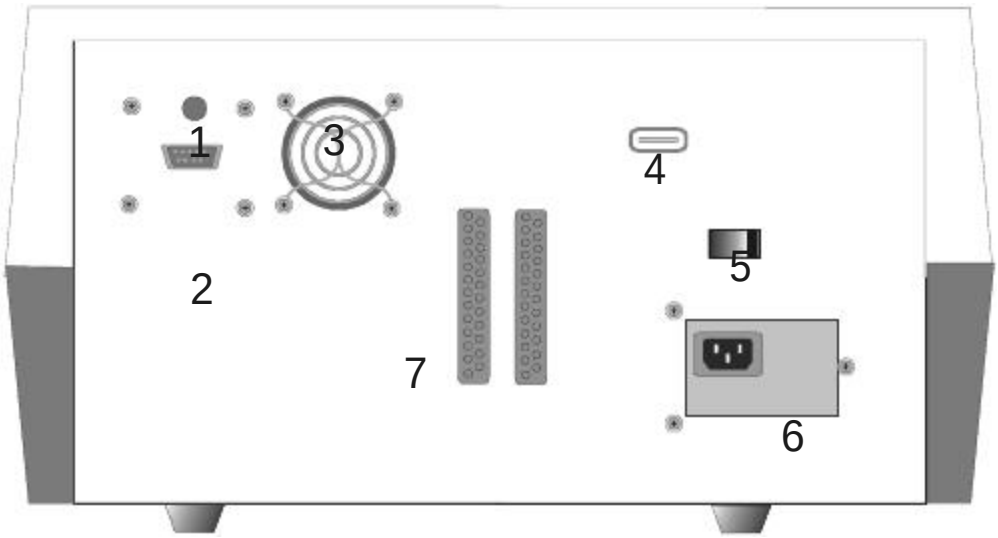
5.3. Rear View:



1) Contrast Knob-use to adjust display contrast

2) Serial RS232 output

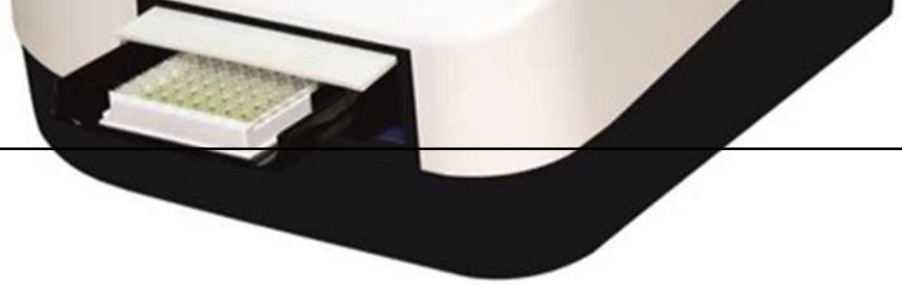
3) Cooling Fan

4) USB output

5) ON/OFF switch

6) SMPS

7) External printer connection



1) ‘YES’ key is used to select any ‘YES’ option on screen directly.
2) ‘NO’ key is used to select any ‘NO’ option on screen directly.
3) ‘PRINT’ key is used to get a printout of current screen displayed.
4) ‘FEED’ key is used to forward the paper in thermal printer by one print line.
5) Navigation keys are used to select any option available on current screen.
6) ‘ENTER’ key is used to run any option selected by navigation keys.
7) ‘ESC’ key is used for escaping from any screen.
8) ‘HOME’ key will not work

6. INSTALLATION PROCEDURE AND VERIFICATION CRITERIA.

6.1. Unpacking Instructions

Check accessories as per packing list.

Kindly store all packaging materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the Instrument

The instrument has to be placed on a level bench.

Room temperature has to be between 10 to 35ºC with a relative humidity below 85%.

Protect the instrument from direct sunshine.

6.3. Power Supply Requirements

Plug the instrument into a power source by the locally available approved plug in cable.

Power cord should be CE, CSA, and UL marked.

115 - 230 Volt ± 10%, 50-60 Hz

6.4. Protective Grounding

Please make sure that electrical power source is properly grounded.

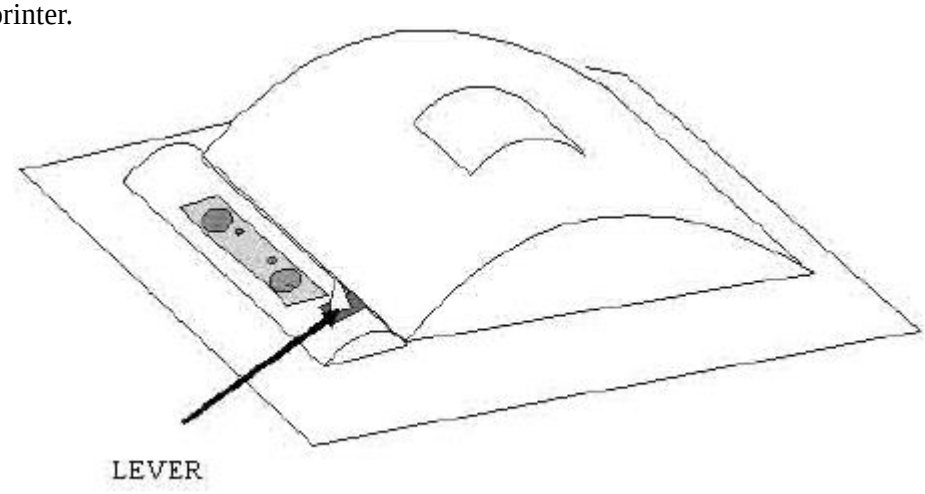
6.5. Printer

ELISA PlateAnalyser is equipped with a built in 52 columns easy load thermal printer.

Opening the Paper Cover:

Slide the LEVER towards back of the printer to open lock of the Paper Cover.

Lightly push up on the front of the paper cover (marked) with your thumb and rotate it towards the back of the printer.



Closing the Paper Cover + replacement of paper roller:

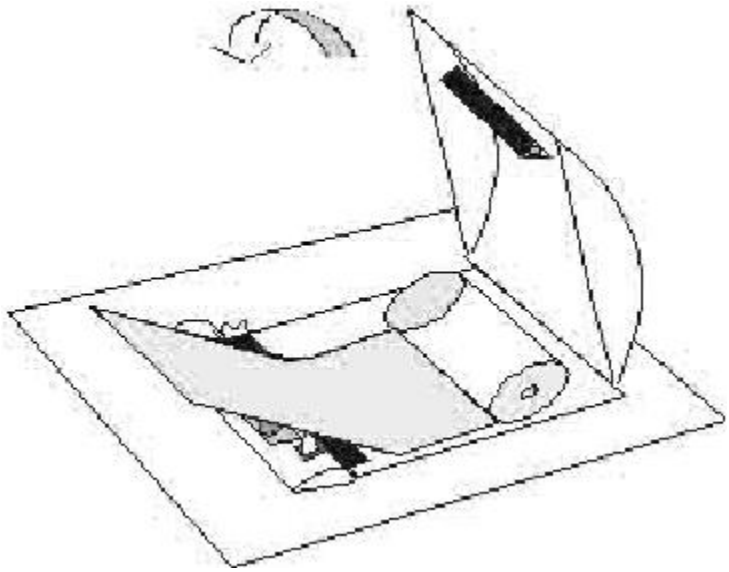
Close the paper cover and push down till you get locking sound.

Open the paper cover.

Remove the paper roller from the slot and place the paper roll over it as shown.

Place back the paper roller with paper into the slot provided and close the paper cover as described before.

Keep pressing the paper feed switch until the paper feeds straight and smoothly.



HINT:

When the paper is set correctly and when the closing of the paper cover is proper the FEED LED will not glow.

It keeps on flashing when the data is being printed.

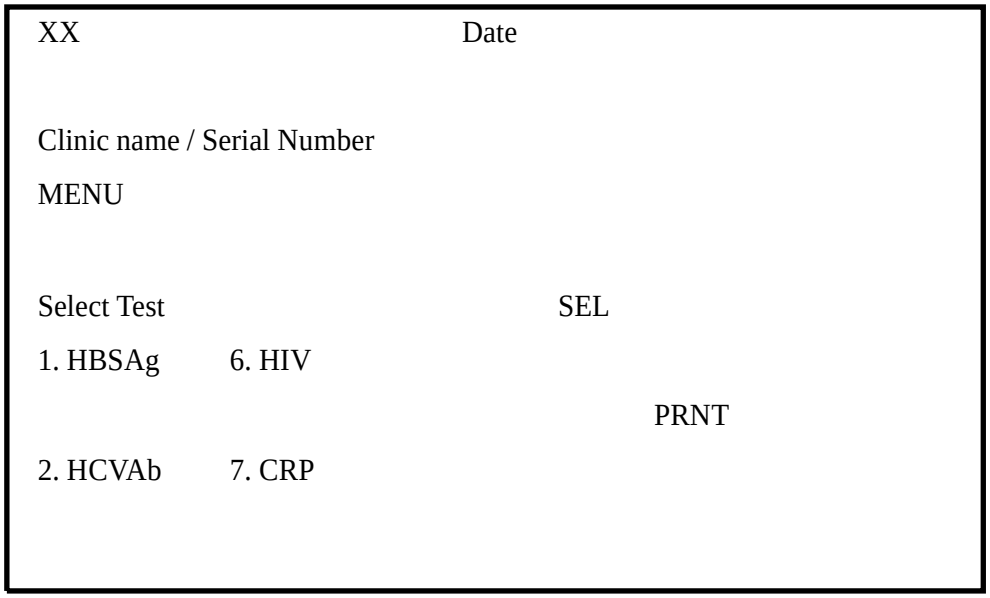
When the paper is almost finished, red lines appear on both sides of the paper.

6.6. Start up Instructions

Switch on the instrument.

The instrument initializes all the parameters internally and carries out a power on self-test and displays the following :“Please wait system initializing.”

The instrument will print the model name “XXX”, VERSION NUMBER, CLINIC NAME CURRENT DATE WITH TIME.



User can select a saved test by first touching the required “TEST” “NAME” on the screen and then touch the “SEL“option to carry out further operation on the test.

“DEL”: Deletes the selected test.

If the number of tests is more than 10, “NEXT“and “PREV” can be used for browsing through the list pages

“PRINT”: For printing the test screen.

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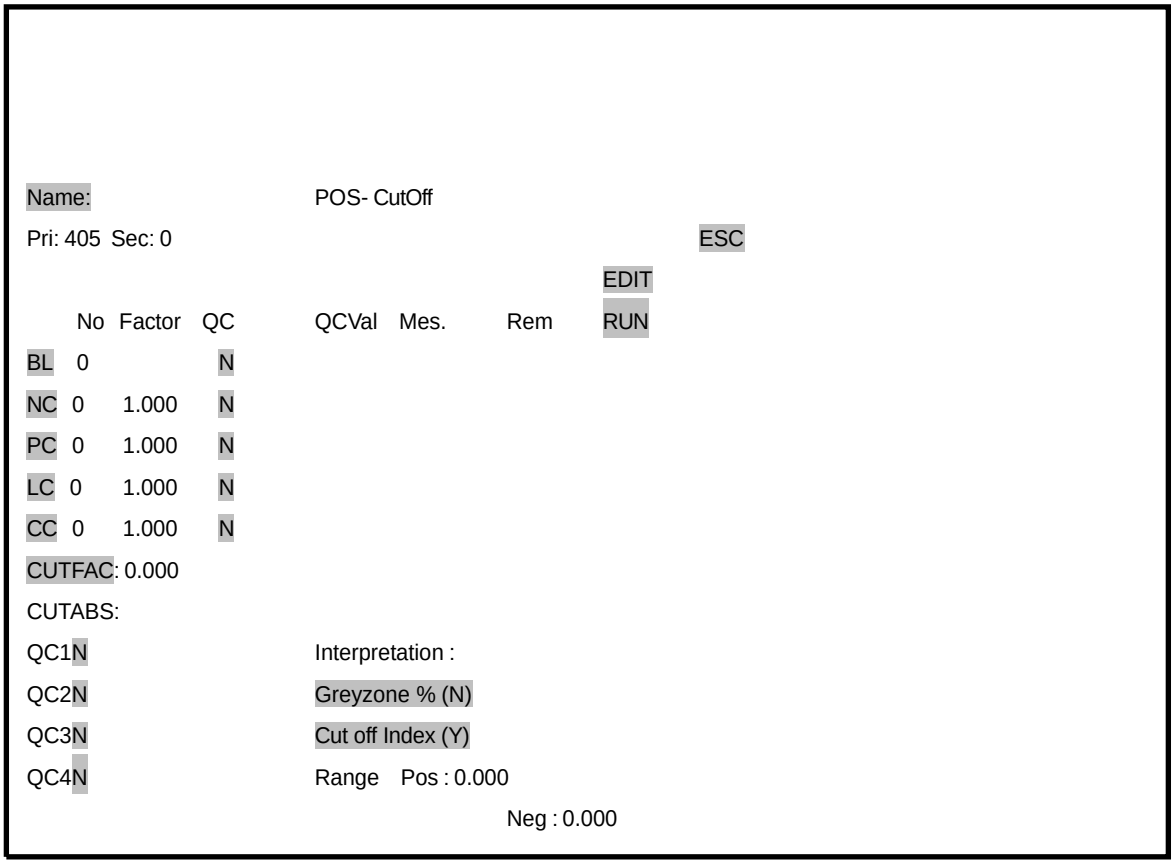
6.7. Touch Panel Check

ELISA plate Analyser provides a ***Touch sensitive LCD panel*** **and a *KEYPAD*** for easy use interface**.**

The Menus are displayed and the text of the parameter forms the TOUCH ZONE.

Touch Screen lay out



Above is the generic representation of a Test Screen. The Highlighted zones are TOUCH ZONES, which are active. On touching the “Touch Zone” of a parameter, a sub menu/menu is displayed or the requested action is carried out. The rest of the “Touch Zone” is deactivated.

For Example: To activate the selection:

Enter the primary filter value to touch any point in the shaded area “Pri” on the LCD screen

On proper selection the analyser responds with blinking of the parameter text and also the TOUCH ZONE and a submenu is displayed.

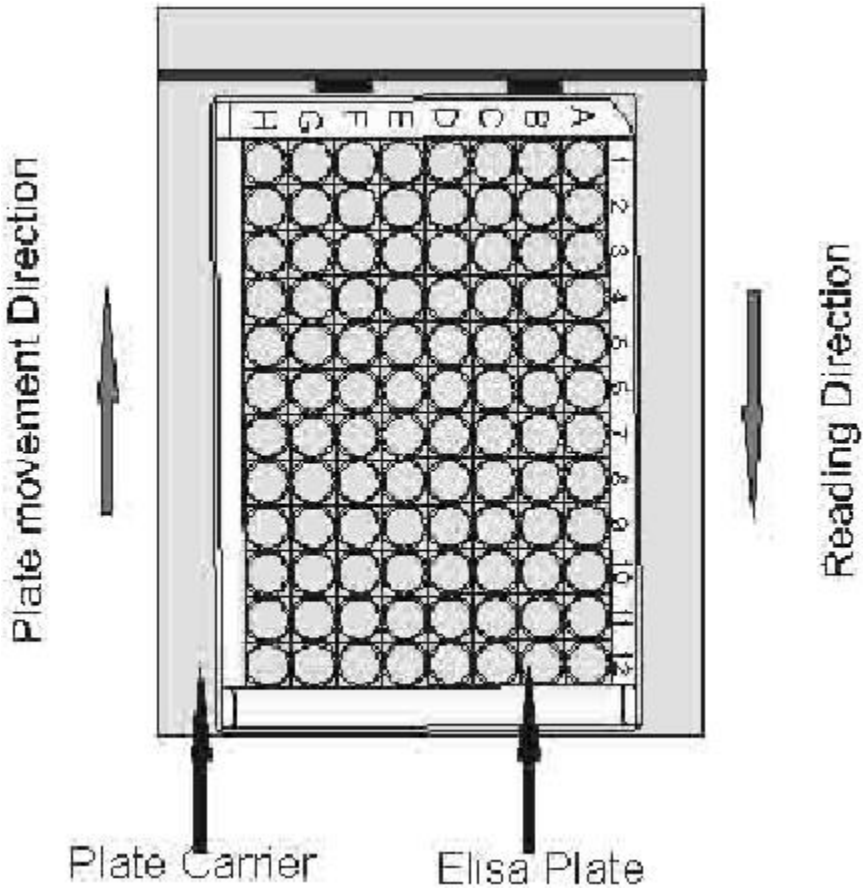
To enter Test Name: Touching the “Name” touch zone provides an alphanumeric screen.

Enter the Test name by touching the Touch zone of that variable. The selected value blinks and is displayed next to the parameter.

Selection Indicator

Selected onscreen item is shown in a shaded background. When the screen first displays, the default selection is shown. Pressing a selection either highlights that item or activates it.

6.8. Micro Titer Plate Carriage



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The instrument is provided with a micro titer plate carriage to move the micro titer plate inside. This carriage is driven by stepper motor with timing belt. It places each well of plate exactly below the optical path of each channel. The plate carrier is moved by a well controlled stepper motor drive.

6.9. Plate Loading & Pipetting Procedure

Control and sample pipetting procedure in case of cut off:

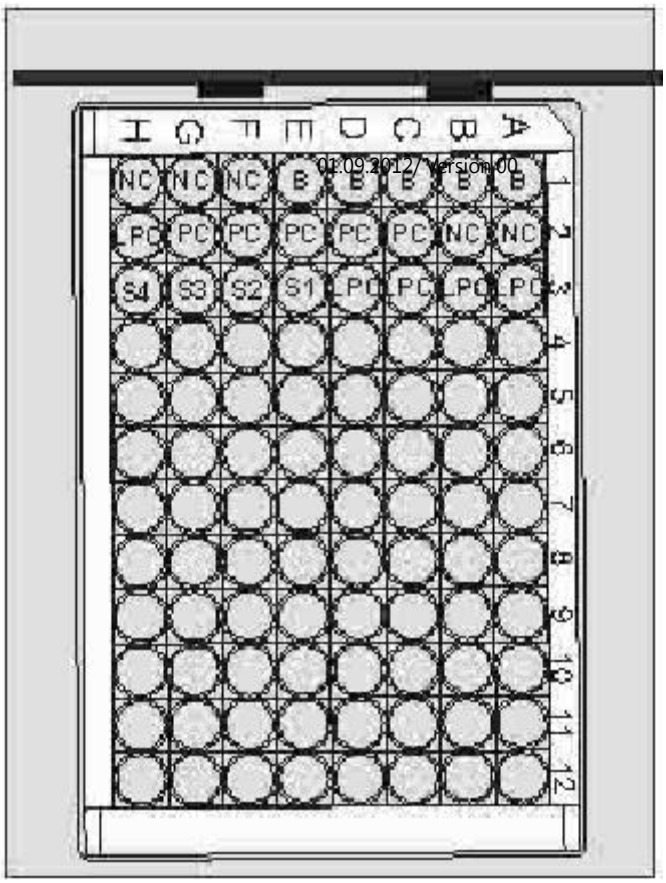
Maximum number of Blanks = 5

Maximum number of Controls:

1. Negative Control = 05
2. Positive Control = 05
3. Cut of control = 05
4. Low Positive Control = 05

Total number of 20 controls can be run in any combination.

Pipetting sequence should be as shown below.



6.10. Readings Check

Checking of readings should be done through controls reading within range specified in data sheet of controls (care should be taken while preparing and pipetting controls and reagents, reagent and control expiry dates need to be checked).

7. PRECAUTIONS

Do not use any sharp objects on the Touch Screen. Always use the STYLUS provided to operate the touch panel.

Always check for proper grounding before installation. Never operate the instrument when ground wire is removed.

Do not attempt to open the instrument and make repairs without proper technical training. Do not allow unauthorized persons to operate or repair the instrument.

Use a clean plate and follow the instructions for blanking and standardizing. Do not read any wells containing bubbles or dust particles.

The volume of sample, calibrators and blanks should be identical for correct readings.

The absorbance is proportionate to the path length. Pipetting should also be proper.

Monitoring of the printed values or displayed values during operation may help detect an error.

Check the linearity and calibration of the instrument regularly against some standard reference.

Check the micro wells before use. They should be scratch-free. The micro well track in the ELISA Plate Analyser has been designed in such a way that the micro wells are totally protected from scratches.

Recheck the reading of high OD (above 2A).

Place Plate carefully on the tray.

Ensure that the main power switch is in OFF position before connecting.

Plug the instrument to the AC mains. Confirm proper grounding for trouble free operation.

Connect the printer only when the instrument is OFF.

8. PROGRAMMING MODES

8.1. Absorbance Mode

In this mode the instrument gives only absorbances of all wells of plates which containing control, calibrators and samples.

Programming a New Test:

A Select "Test Operation"

1 Test Operations ESC

2 Technical Diagnosis

3 Utilities

4 View Plate

5 Serial Communication

B. Select "Add New Test"

TEST OPERATIONS

1 Select Test By Name

ESC

2 Select Test by Mode

3 Select Test by Number

4 List Tests

5 Add New Test

C Select mode of operation "Absorbance" in "Add new test"

Select Test	Mode
1> Absorbance	0
2> Single Standard	0
3> Cut off	0
4> Multi Standard	0
5> Percent Absorbance	0
6> Uptake	0
7> Kinetic	0

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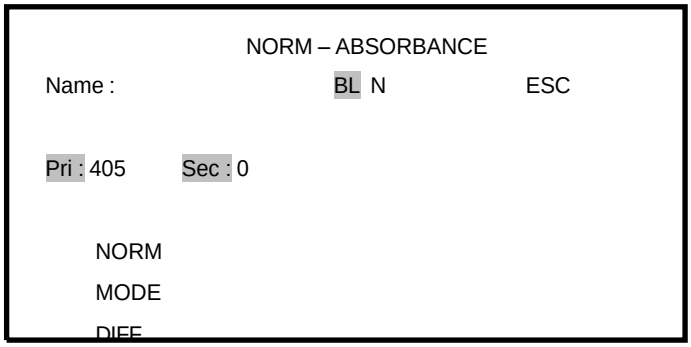
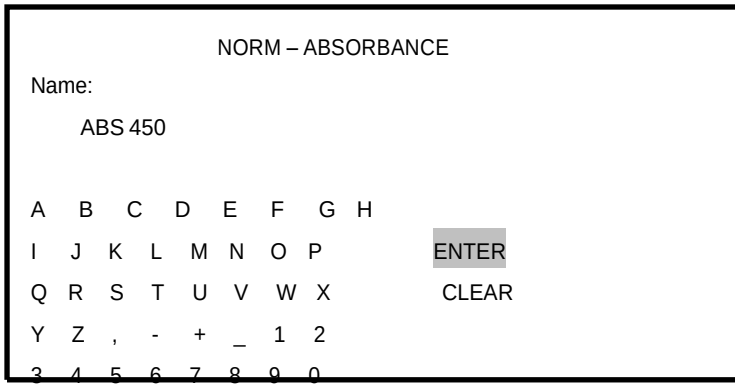
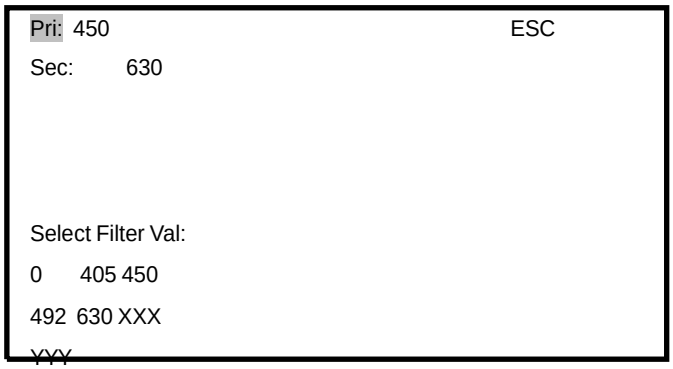
D. Enter "Test Name"



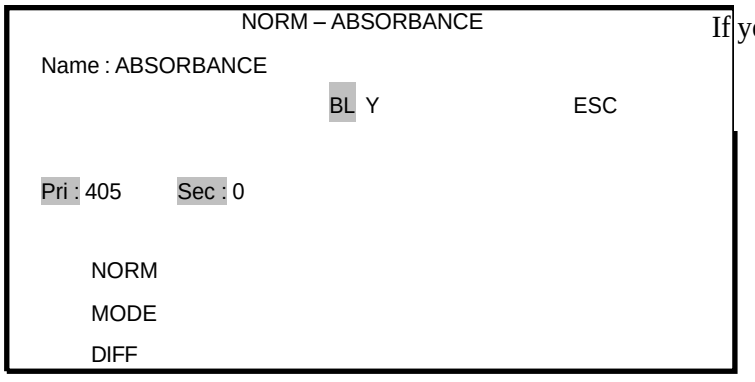


5. Select primary and secondary filter

E. Select primary and secondary filter



F. If blank is required select "BL"



If you select "BL Y", it will read first well first strip 'A1' as a blank and subtract the absorbance of blank well from all other well's absorbance.

G. In absorbance mode there are two modes of operations

Normal Absorbance Mode: Instrument gives the absorbance of each and every well.

Select touch zone "NORM".

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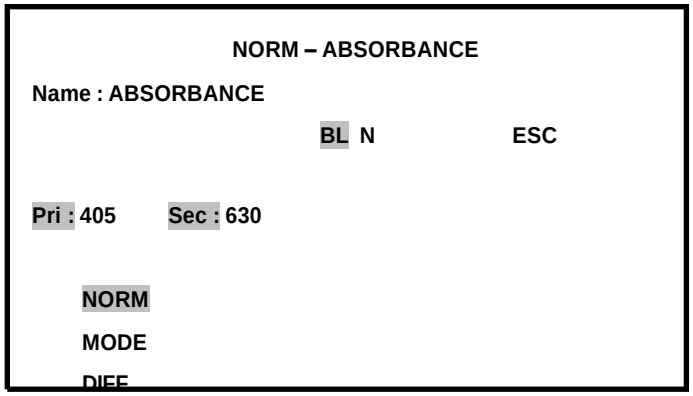
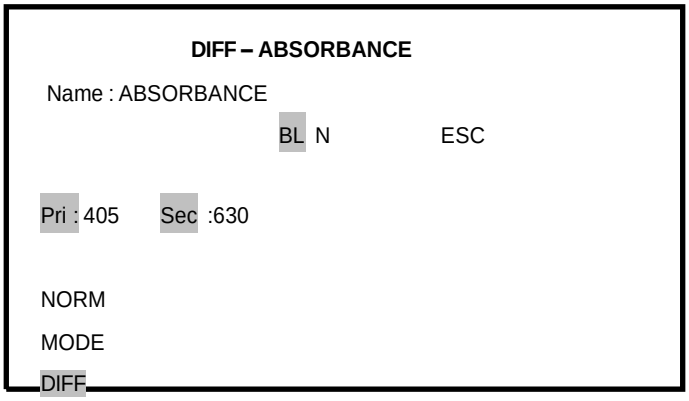
Differential Absorbance Mode: Instrument shows the difference of absorbance between odd number wells and even number wells. For Example,- Strip 1,- Strip 2, - Strip 3, - Strip 4, - Strip 5, - Strip 6. For this Mode select touch zone “DIFF”.

In Normal Mode



In Differential Mode



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H. Example Print-out obtained

NORM-ABSORBANCE

Name : HCV

BL N

Pri : 450 Sec : 630

HCV, 21/07/08,

	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
A	0.028	0.145	0.100	0.017	0.089	0.135	0.362	0.078	0.410	1.440	0.746	0.224
B	0.058	0.151	0.386	2.553	0.111	1.479	2.593	0.081	2.517	0.781	0.730	0.005
C	0.065	2.596	0.135	0.142	0.141	0.182	0.108	0.112	1.585	1.530	0.405	2.635
D	0.072	0.150	2.630	0.143	2.650	0.077	0.159	0.170	1.504	0.071	0.426	0.222
E	2.541	0.140	0.149	0.091	0.166	0.173	2.653	0.191	0.097	2.659	0.252	0.222
F	2.614	2.682	0.185	0.130	2.648	0.167	0.176	0.071	2.686	0.853	0.907	0.426
G	0.056	0.163	2.571	0.155	0.147	0.119	2.618	0.081	0.085	0.070	0.407	2.591
H	0.071	0.123	0.113	0.054	0.116	0.060	0.112	0.111	0.093	2.568	0.396	0.015.

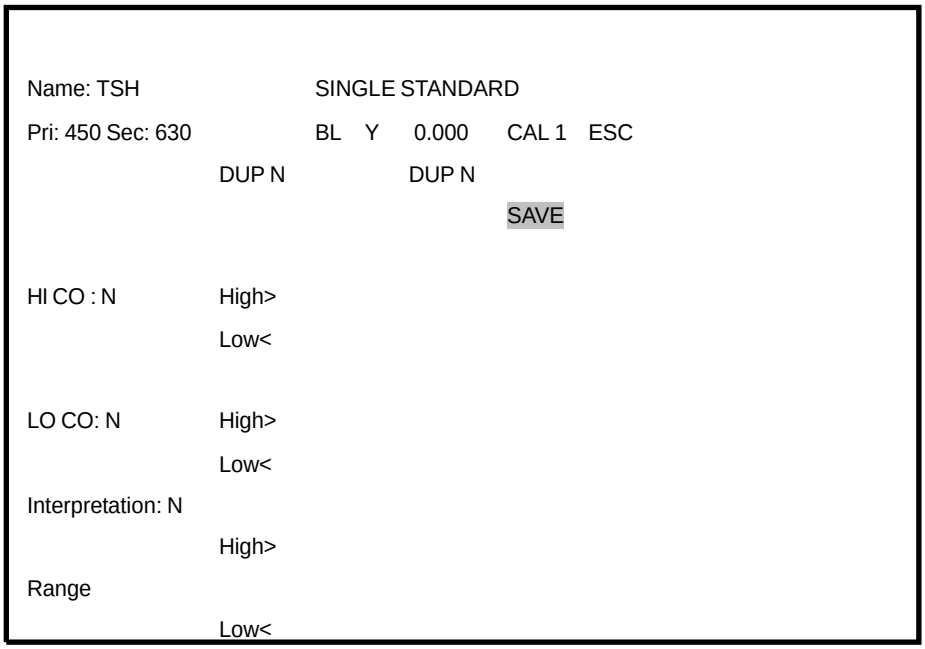
8.2. Single Standard

In this mode the instrument accepts the calibrator singly or in duplicate and than calculates the concentration based on the single point standard curve passing through the point 0.0.

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law. The absorbances are read at user selected wavelengths. If Blank is selected, instrument will automatically blank on the first well and subtract its absorbance from each subsequent well. The second well is treated as the calibrator/standard well. The third well is also treated as calibrator/standard well if the calibrator/standard is in duplicate.

CALCULATION:

Sample Concentration = (Calibrator concentration /Calibrator Abs.) x Sample Abs.



Entry of all the parameter is similar to Multi standard mode (Please refer Multi standard for entry of parameters)

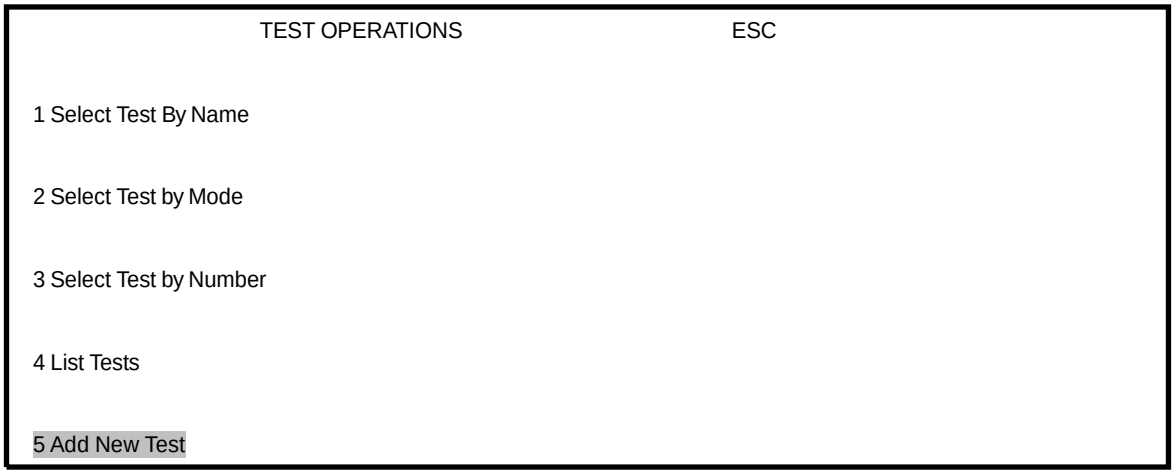
User Manual

8.3. Cut Off Mode

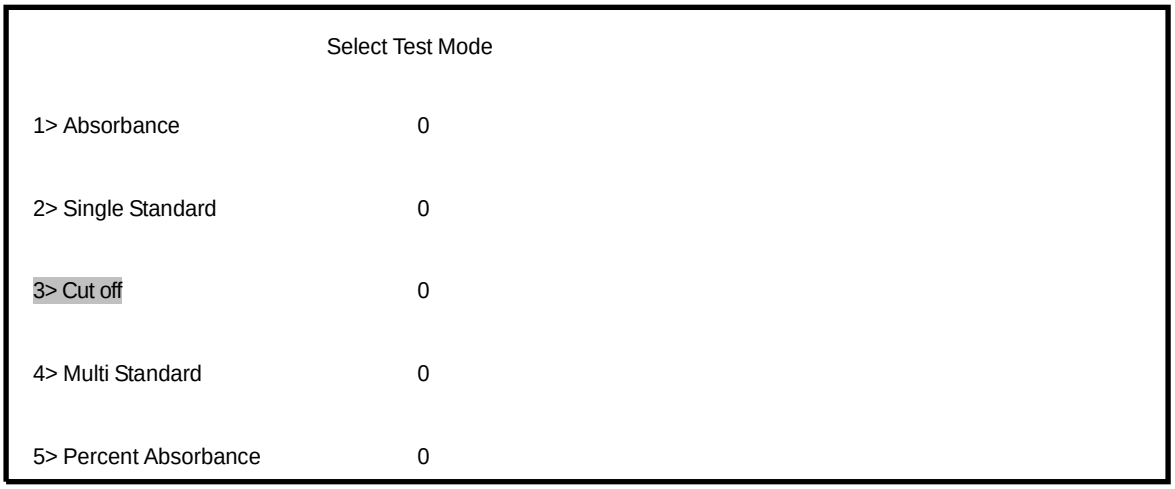
In this mode cut-off point is determined for interpretation of specimens as per formula given in the reagent manual. The negative controls are read followed by the positive controls, Cut-off control, low positive control. Blanking on the first well is optional. The instrument calculates the average of the negative controls and the average of the positive control, Cut-off controls and Low positives are also calculated.

Programming a New Test:

A. Select "Add New Test"



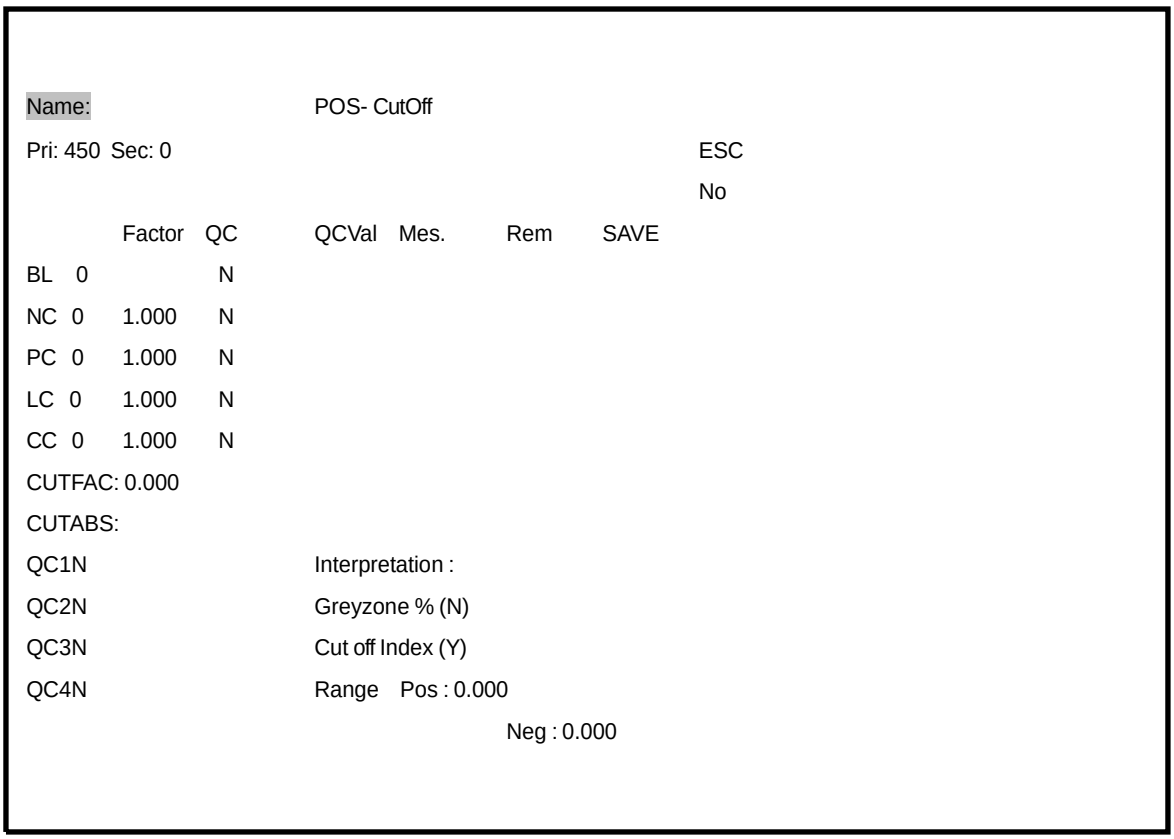
B. Select mode of operation "Cut-Off" in "Add new test"



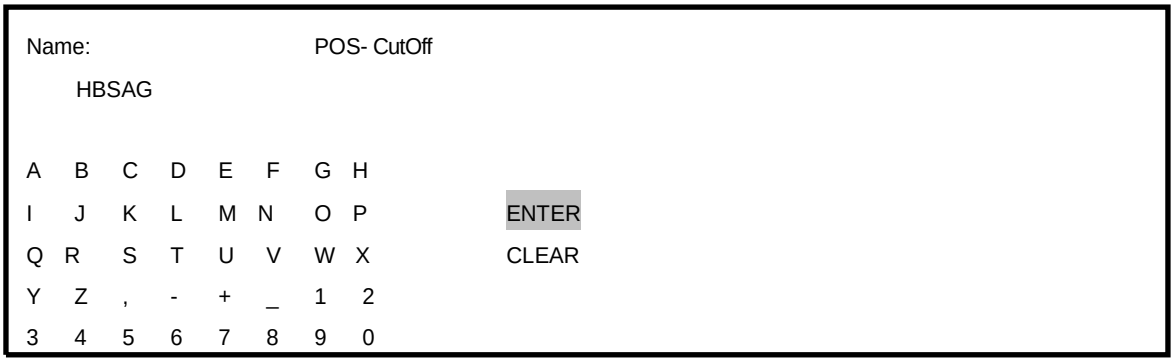
User Manual

C. Entry of test name

Select touch Zone "Name:"



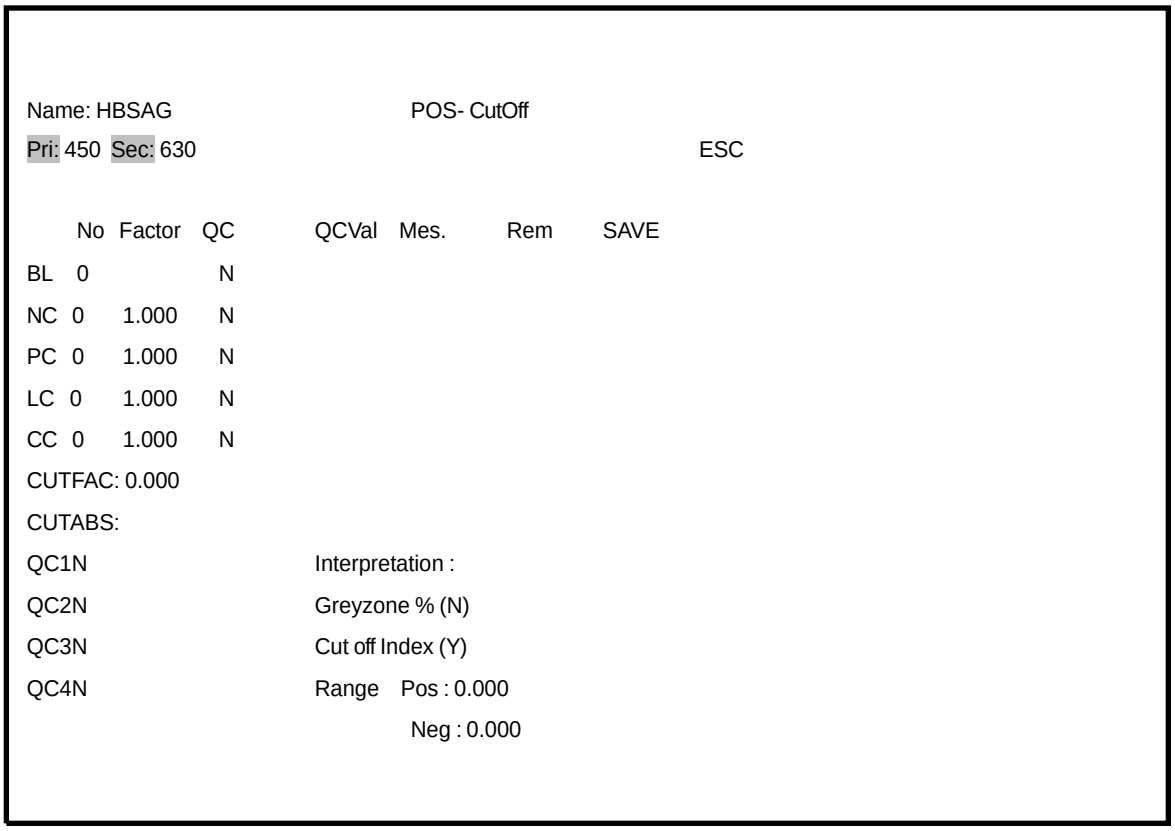
Alphanumerical characters will appears on the screen as shown below after touching "Name" on the screen. Enter the name of the test by selecting the individual characters one by one. After selecting all the characters select Enter option in touch screen for confirmation of test Name.



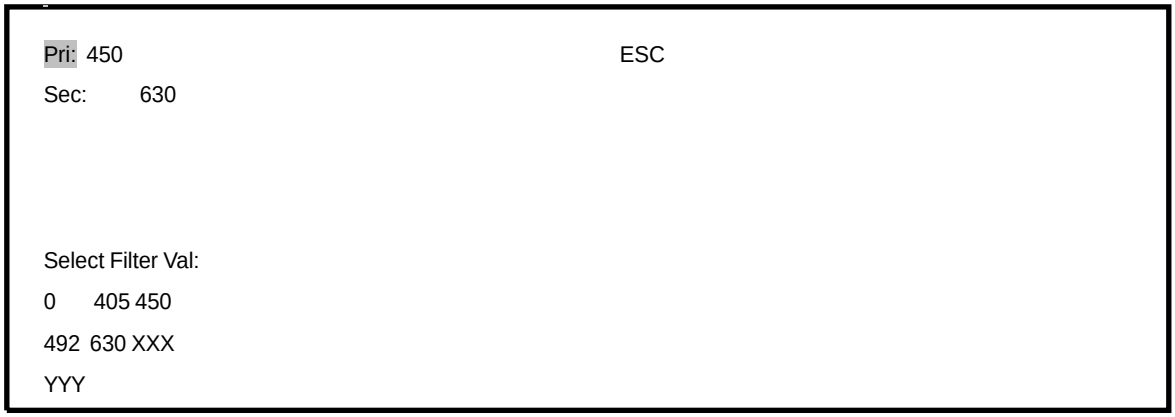
User Manual

D. Selection of Primary and secondary filters.

Select zone "Pri:" on the touch screen



Select the filter required by selecting the filter from Select filter value region after touching 'Pri" zone.



User Manual

E. According to the reagent manual change Blank, NCs, PCs to 'YES' for QC check.

Name: HBSAG POS- CutOff

Pri: 450 Sec: 630 ESC

	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	0		N				
NC	0	1.000	N				
PC	0	1.000	N				
LC	0	1.000	N				
CC	0	1.000	N				

CUTFAC: 0.000

CUTABS:

QC1N Interpretation :

QC2N Greyzone % (N)

QC3N Cut off Index (Y)

QC4N Range Pos : 0.000

Neg : 0.000

F. Entry of Blank and Blank QC values

Select "BL" to enter blank details.

Name: HBSAG POS- CutOff

Pri: 450 Sec: 630 ESC

	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	0		Y	0.000	0.000		
NC	0	1.000	Y	0.000	0.000		
PC	0	1.000	Y	0.000	0.000		
LC	0	1.000	N				
CC	0	1.000	N				

CUTFAC: 0.000

CUTABS:

QC1N Interpretation :

QC2N Greyzone % (N)

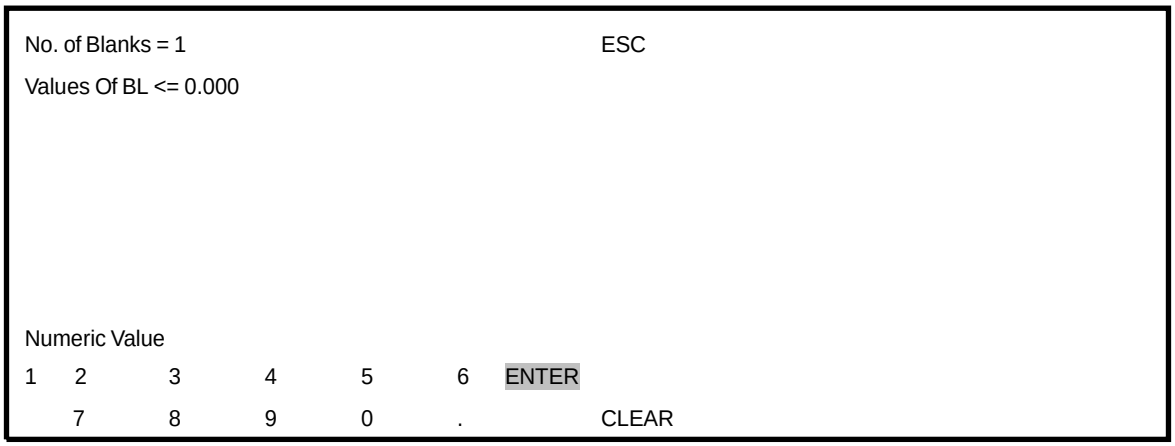
QC3N Cut off Index (Y)

QC4N Range Pos : 0.000

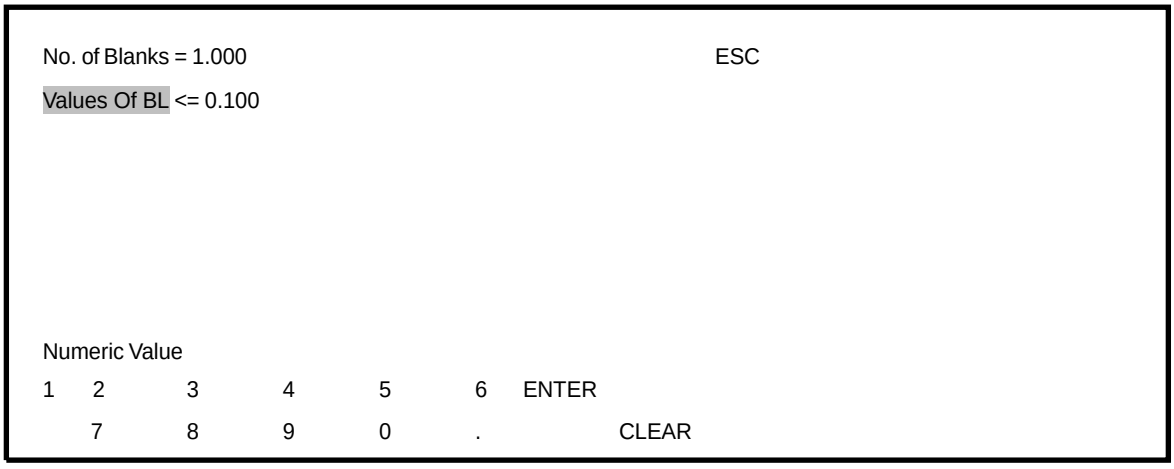
Neg : 0.000

User Manual

G. After selecting "BL", enter total number of blanks by selecting No. of Blanks. (Maximum 5 blank).



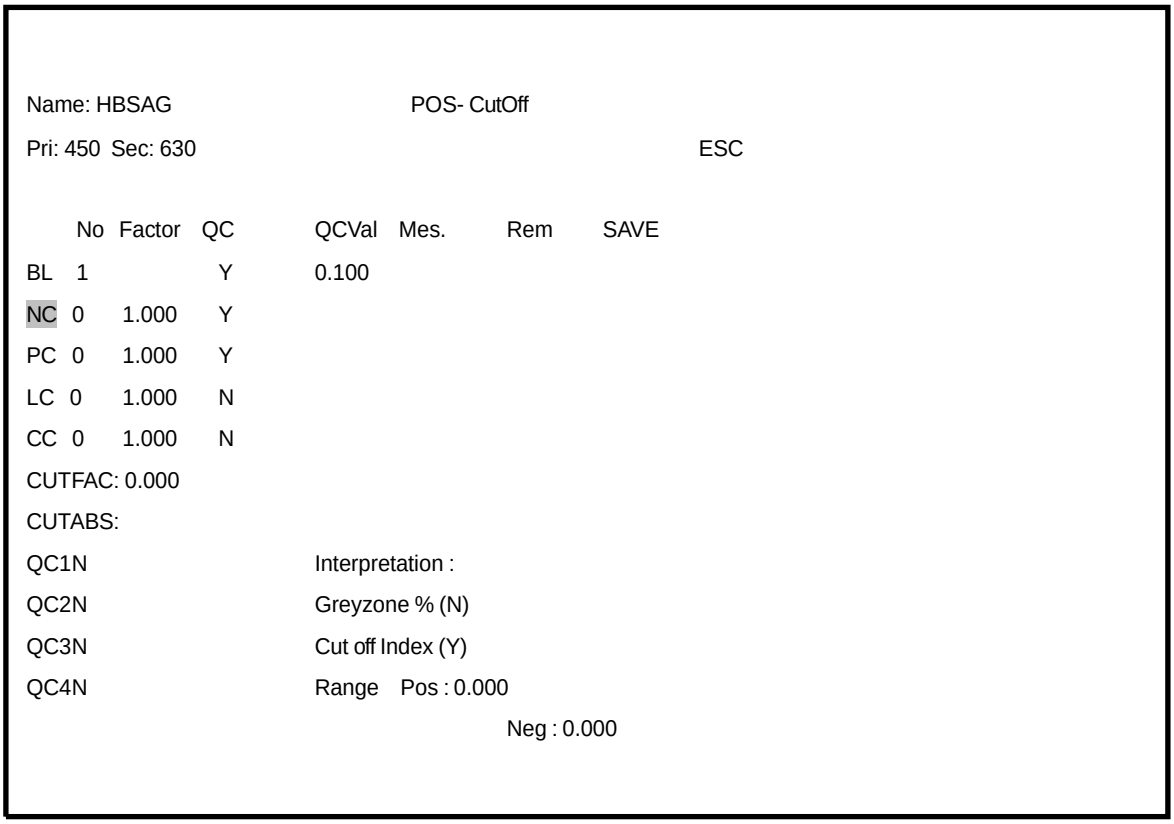
H. Enter the QC value of the blank by selecting the touch Zone "Values of BL <="



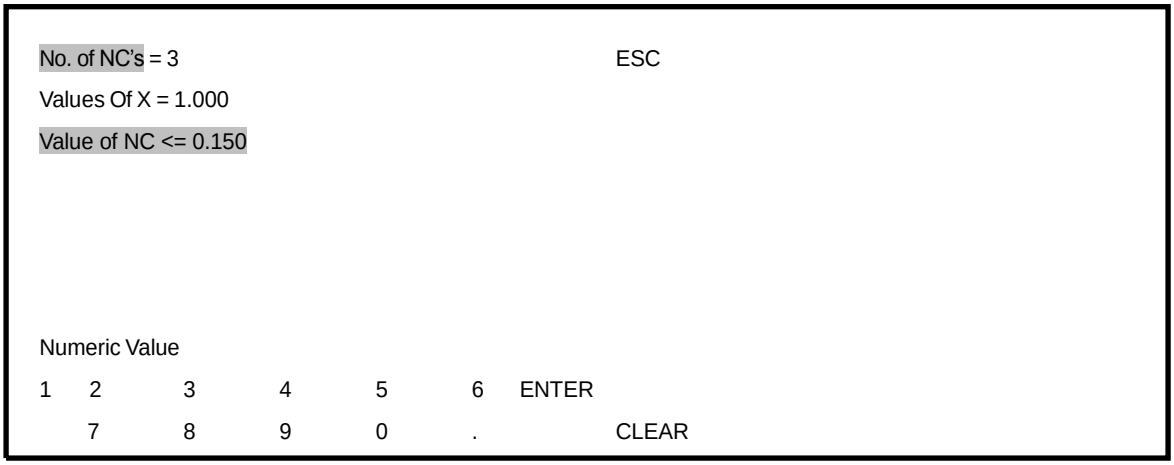
User Manual

I.Entry of Negative control and its QC values

Select touch Zone "NC"



J. Enter N° of Negative controls by selecting touch Zone "N°of NC's" (maximum 5 Negative Controls). Enter the QC value of the Negative Control by selecting the touch Zone "Value of NC" and enter the value of X given in the reagent manual by selecting Zone "Values Of X".



User Manual

K. After the entry of N° of NC's Select ESC. The below screen will appear on the display.

Name: HBSAG POS- CutOff

Pri: 450 Sec: 630 ESC

No

	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Y	0.100			
NC 3	1.000	Y	0.150			
PC 0	1.000	Y				
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.000

CUTABS:

QC1N Interpretation :

QC2N Greyzone % (N)

QC3N Cut off Index (Y)

QC4N Range Pos : 0.000

Neg : 0.000

L. Entry of Positive Controls (PC).

Select touch Zone "PC".

Name: HBSAG POS- CutOff

Pri: 450 Sec: 630 ESC

No

	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Y	0.100			
NC 3	1.000	Y	0.150			
PC 0	1.000	Y				
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.000

CUTABS:

QC1N Interpretation :

QC2N Greyzone % (N)

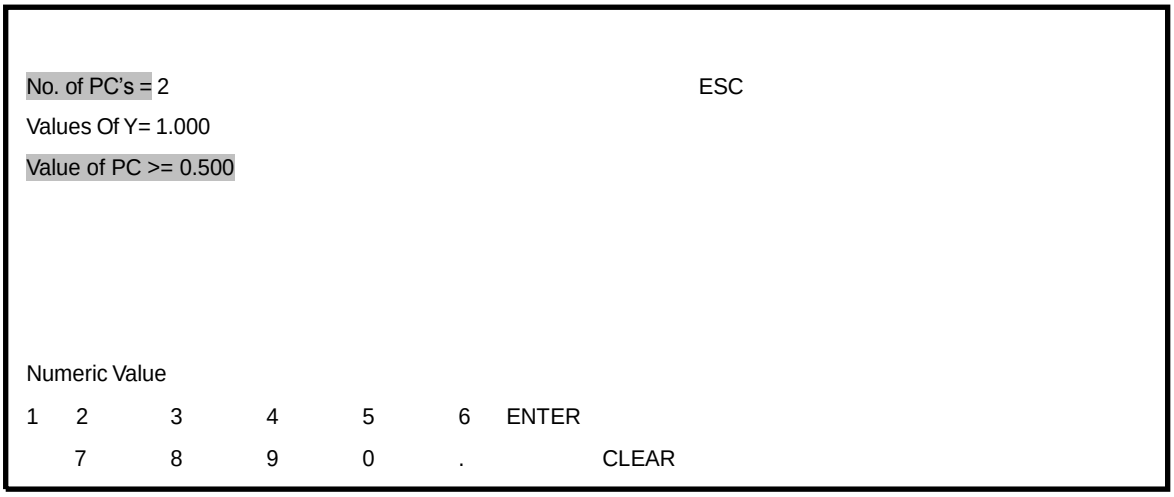
QC3N Cut off Index (Y)

QC4N Range Pos : 0.000

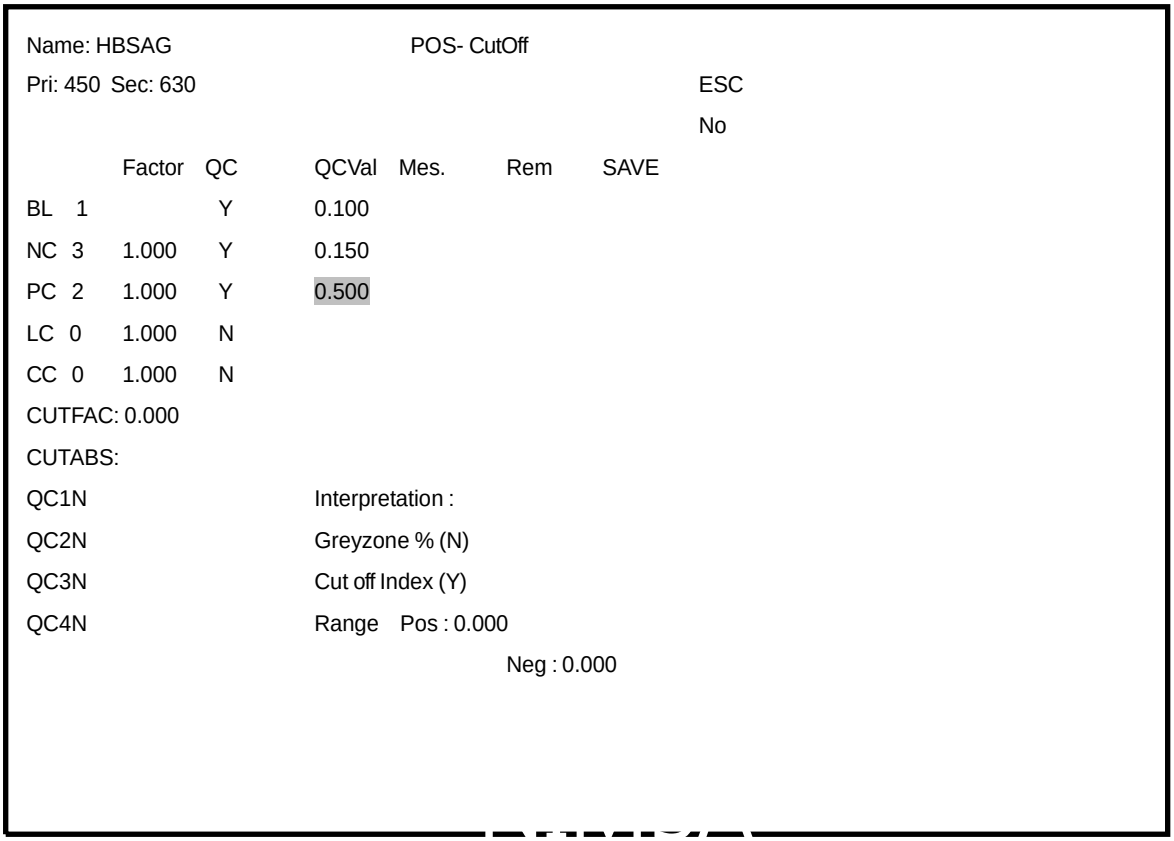
Neg : 0.000

User Manual

M. After selecting No. of PC's the screen below will appear on the display. Enter number of Positive Controls by Selecting Zone "No. of PC's" (Maximum 5). Enter the QC value of the Positive Control by selecting the touch Zone "Value of PC >=" and enter the value of Y given in the reagent manual by selecting Zone "Values Of Y".



N. After entering the details of PCs, escape from the screen by selecting "ESC". Below screen will appear on the display:

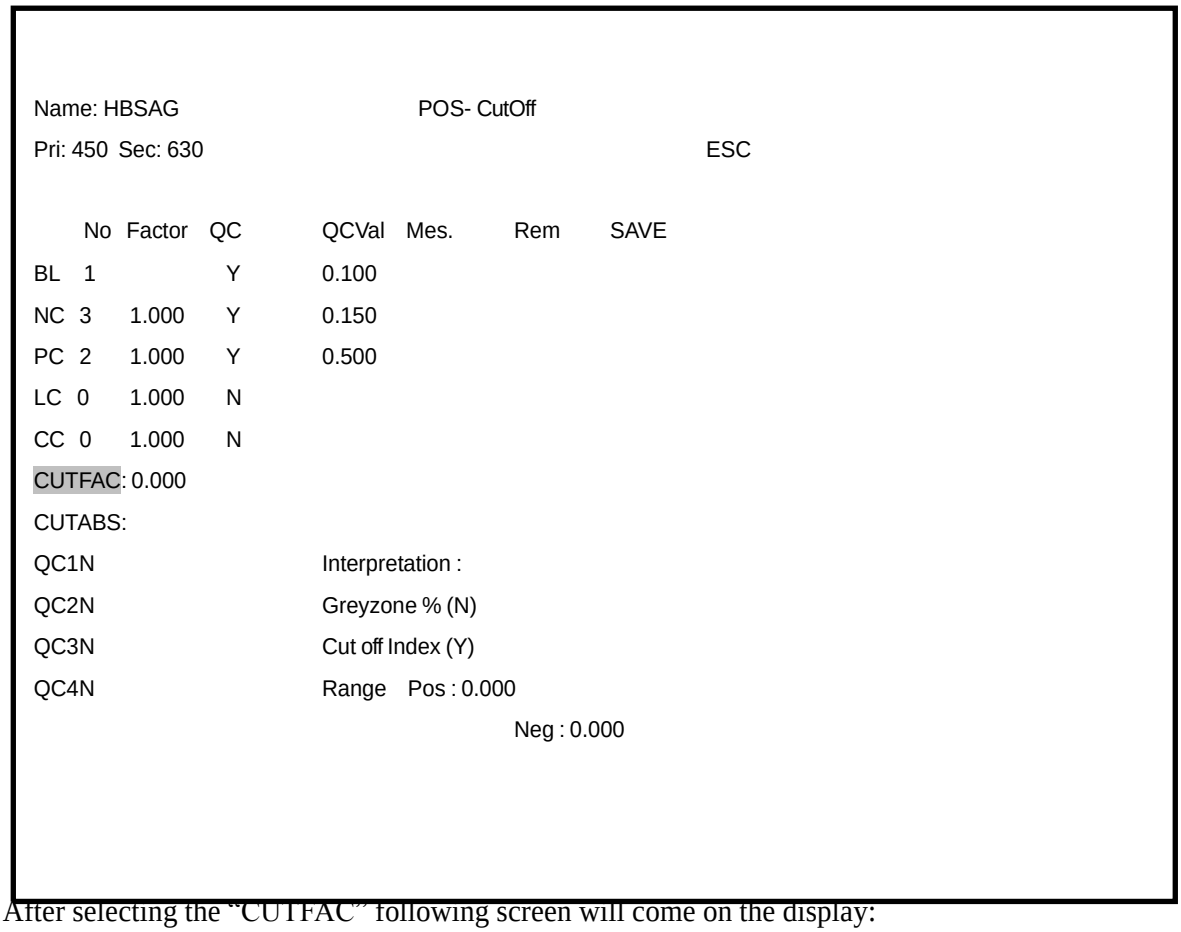


User Manual

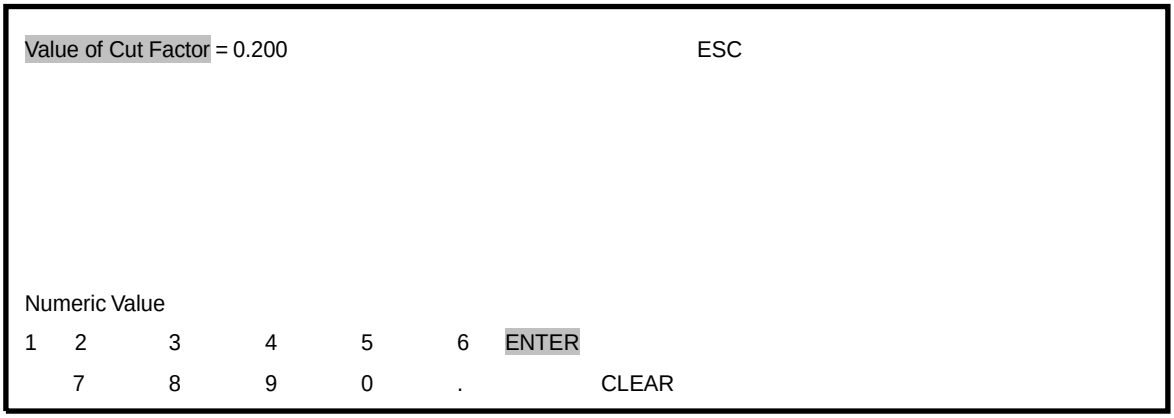
NOTE: Same way you can enter values for LC (lower positive controls) and CC (Cut of Controls).

O. Entry of Cut off Factor:

Select touch Zone "CUT FAC"



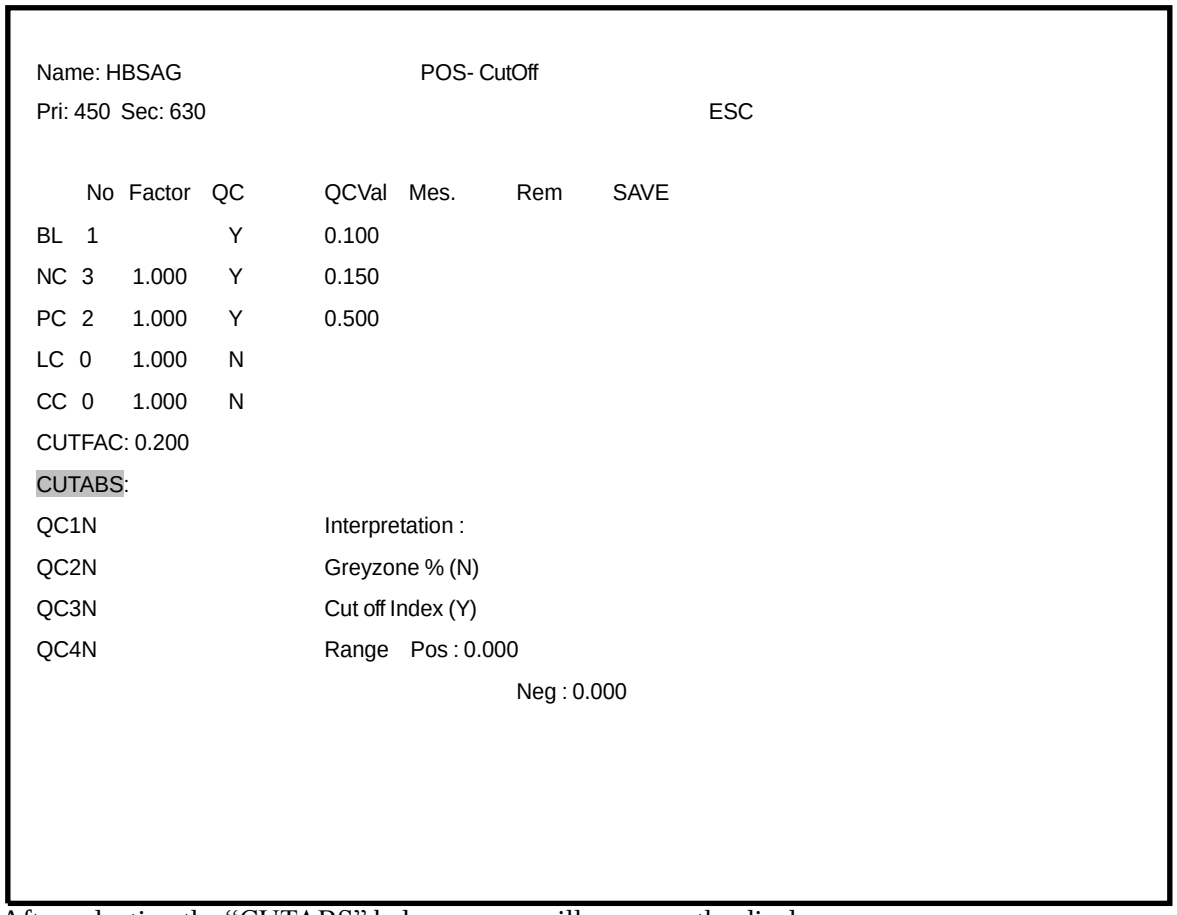
After selecting the "CUTFAC" following screen will come on the display:



User Manual

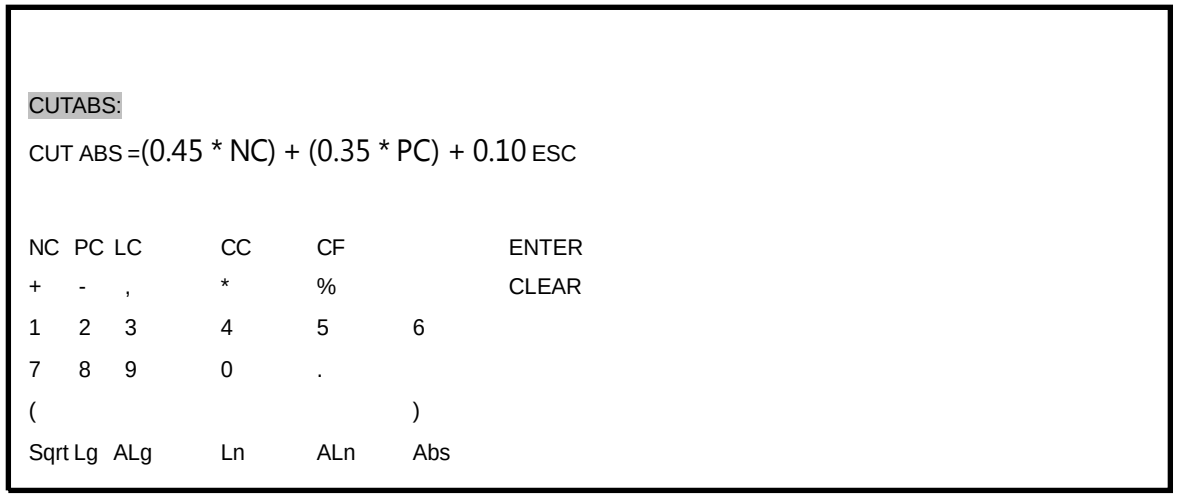
P. Entry of Cut off absorbance equation:

Select touch Zone "CUTABS"



After selecting the "CUTABS" below screen will come on the display.

Enter the equation as given in the reagent manual.



User Manual

NC = Mean of NCs * Factor X

PC = Mean of PCs * Factor Y

LC = Mean of LCs * Factor W

CC = Mean of CCs * Factor Z

CF = Cut off Factor

Sqrt = Square root

Lg = LOG ALg = Anti LOG

Ln = Natural LOG Aln = Anti Natural LOG

Abs. = any absolute value

For Example :

For equation CUT OFF ABS = (0.45 * NC) + (0.35 * PC) + 0.10, the formula can be entered in two ways.

1. Enter the values as it is i.e. CUTABS = (0.45*NC) + (0.35*PC) + 0.010. Keep the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'. (Numbers, mathematical functions and symbols for NC, PC, CC, LPC can be selected from the screen).

OR

2. In second method the formula can be entered as CUT ABS = NC + PC + CF. (Since the Value of X, Y, Z, W is entered in the QC option of NC, PC, CC, LPC and Cut off factor in the CUT FAC option, there is no need to enter the same data again). Means here Multiplication Factor for NC = X = 0.45

Multiplication factor for PC = Y = 0.35 and the value of cut of factor = CUT FAC = 0.100.

This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mentioned above.

If 'CUTOFF ABS' = (NC + PC) / 6. This can be entered as it is CUTABS = (NC + PC) / 6 by keeping the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'.

User Manual

OR

As you know in mathematics (NC + PC) / 6 = (NC / 6) + (PC / 6) =

(1/6) * NC + (1/6) * PC = (0.166 * NC) + (0.166 * PC),

So, you can enter same equation as CUT ABS = NC + PC, by entering

Multiplication Factor for NC = X = 0.166, multiplication factor for PC = Y = 0.166.

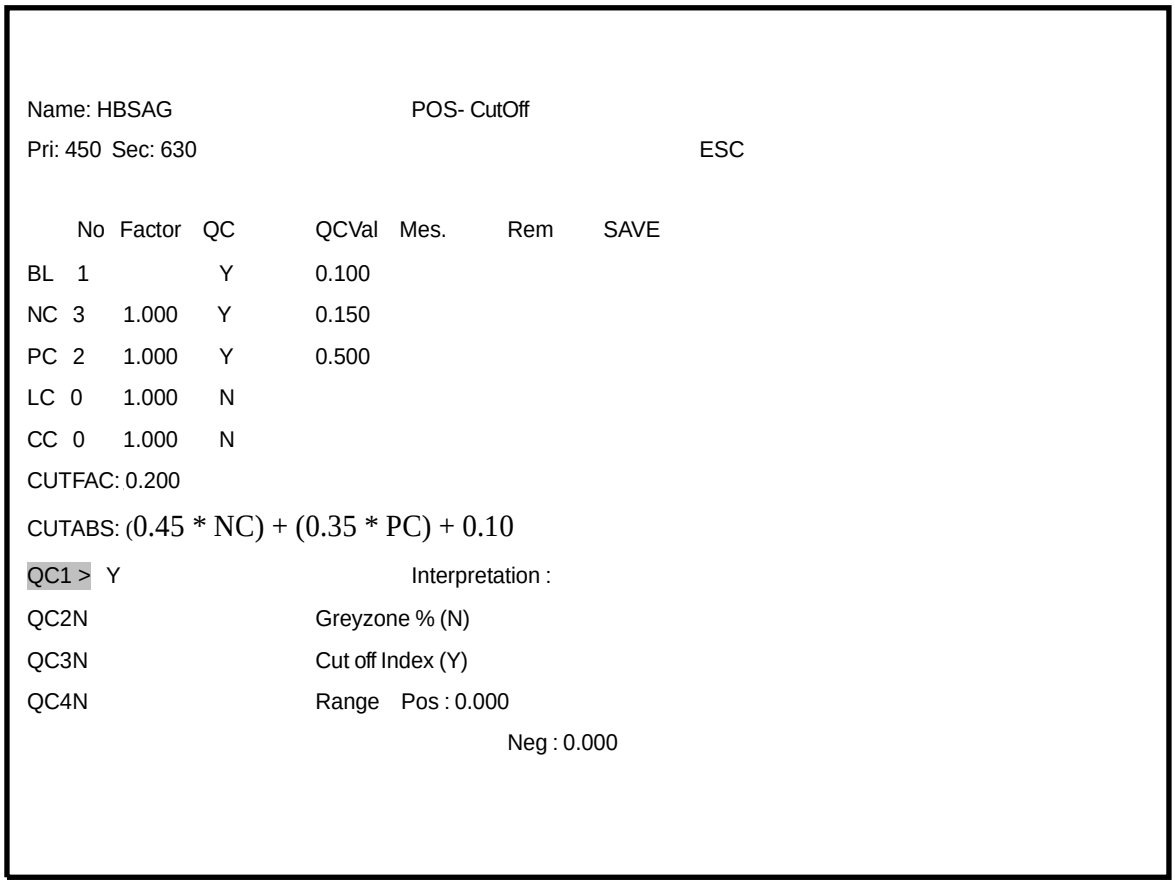
This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mention above.

Q. QC1, QC2, QC3 & QC4. can be used for any QC Checking of the test provided in reagent manual.

For example some kit may give QC check equation like| PCx – NCx |> 0.500,

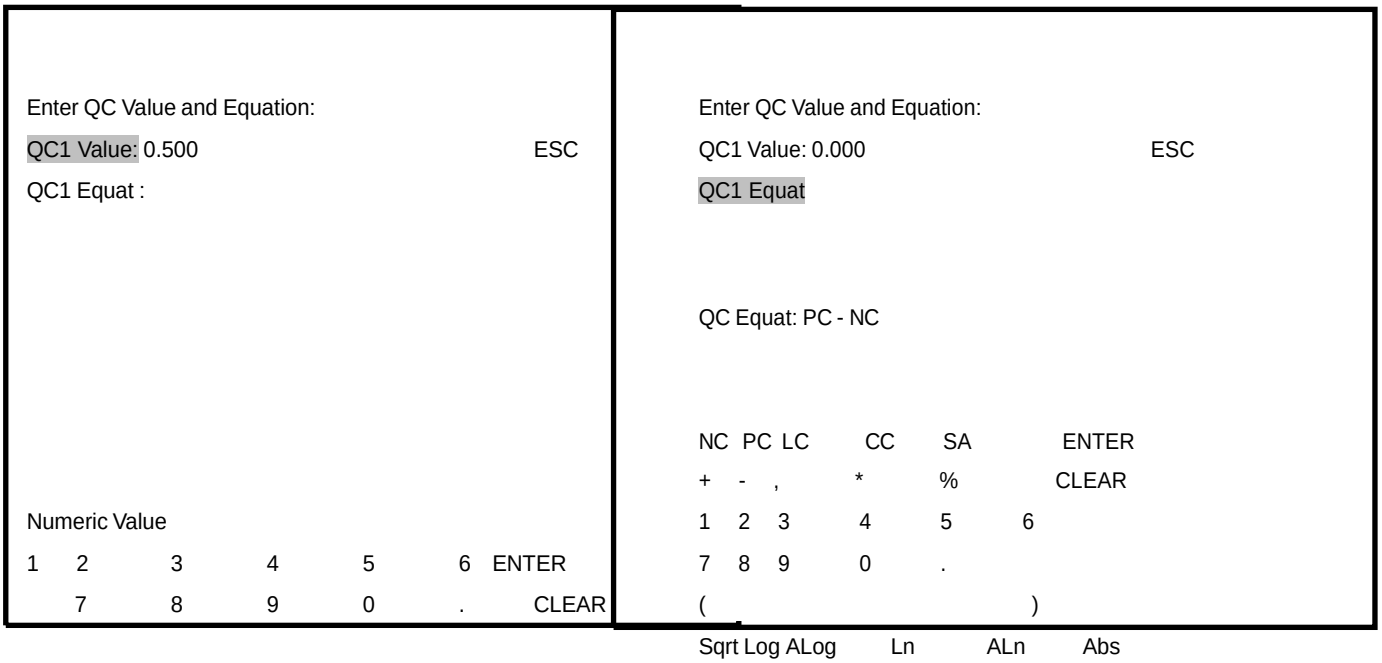
PC / NC > 15, etc. This equation can be entered by selecting these QC options. Select touch zone 'N'.

You will obtain 'Y', as shown in screen below by selecting touch zone 'QC1' and entering QC equation.



User Manual

Enter equation of QC and value of QC check by selecting touch zone ‘QC1 Value’ and ‘QC1 equat’.



Same way you can enter QC equations for QC2, QC3 and QC4.

***NOTE:**

On screen it is mentioned that “QC1 > Y”. In most of the reagent inserts it is mentioned that QC value should be greater than some constant value. Sometimes in the boxinsert it is mentioned that the value should be less than some constant value. In such case, you can change the symbol from “QC1 > Y” to “QC1 < Y”, only by selecting a symbol of comparison.

If any QC check is selected to ‘YES’ option, the system will not save the test without entering the QC equation and QC check value of equation.

R. Interpretation of samples

Enter RANGE for interpretation of results either in percentage (Greyzone) or positive and negative values of INDEX, as a ratio of (Sample Abs. / Cutoff Abs.). If Cutoff Index range or Greyzone is not mentioned do not enter any values. Instrument will do the interpretation with references to the Cut off absorbance.

R.1. Interpretation by GREYZONE percentage

Select touch zone 'Greyzone % (N)'

Name: HBSAG POS- CutOff

Pri: 450 Sec: 630 ESC

No

	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Y	0.100			
NC 3	1.000	Y	0.150			
PC 2	1.000	Y	0.500			
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.200

CUTABS: NC + PC + CF

QC1 > Y 0.500 Interpretation :

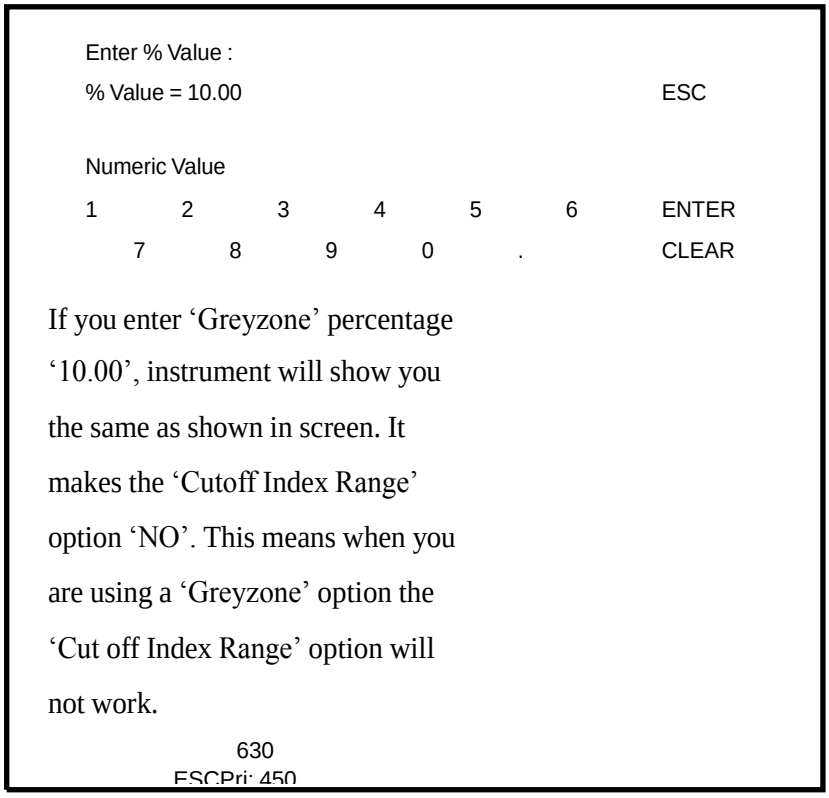
QC2N Greyzone % (N)

QC3N Cut off Index (Y)

QC4N Range Pos : 0.000

Neg : 0.000

Enter Greyzone percentage value



I

Name: CPC POS- CutOff
Sec:

No

	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 1		Y	0.100			
PC	1.000		0.500			
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.200
CUTABS: NC + PC + CF
QC1 > Y 0.500 Interpretation :
QC2N Greyzone % (Y) 10.00
QC3N Cut off Index (N)
QC4N Range

In case of 'Greyzone', it gives the 'Positive' remarks to sample absorbance greater than greyzone area of cutoff absorbance and a 'Negative' remarks to sample absorbances less than greyzone area of cutoff absorbance. The sample absorbances lying in greyzone area get remarks 'Equivocal' = 'EQ'.

User Manual

Name: CPC POS- CutOff

Pri: 450 Sec: 630 ESC

	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				

CUTFAC: 0.200

CUTABS: NC + PC + CF

QC1 > Y 0.500 Interpretation :

QC2 N Greyzone % (N)

QC3 N Cut off Index (Y)

QC4 N Range Pos : 0.000

Neg : 0.000

Cut off Index is the ratio of Sample Absorbance / Cut off Absorbance.

When you select 'Cutoff Index' – 'Y', the 'Greyzone %' will become 'NO', means inactive.

In 'Cutoff Index', provide the range for interpretation, the positive and negative value of ratio (Sample Abs. / Cutoff Abs.)

RESULT RANGE:

POSITIVE >= 1.000 ESC

NEGATIVE <= 0.900

Numeric Value

1	2	3	4	5	6	ENTER
7	8	9	0	.		CLEAR

In case of 'Cutoff Index Range ', It gives the 'Positive' remarks to sample having index value, a ratio of …

(Sample abs. / Cutoff Abs.) greater than or equal to entered 'POSITIVE' value and

it gives 'Negative' remarks to sample having index value, a ratio of

(Sample abs. / Cutoff Abs.) less than entered 'NEGATIVE' value.

The sample having index value in between 'POSITIVE' and 'NEGATIVE" range get remarks 'Equivocal' = 'EQ'.

User Manual

Name: CPC POS- CutOff
Pri: 450 Sec: 630 ESC

	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				

CUTFAC: 0.200
CUTABS: NC + PC + CF
QC1 > Y 0.500 Interpretation :

For example:
If you enter POS >= 1.0 and NEG <=0.9.
Then, the sample will get POSITIVE remarks having INDEX Value,
(Sam. Abs./ Cutoff Abs.) >= 1.000.
The sample will get NEGATIVE remarks having INDEX Value,
(Sam. Abs./ Cutoff Abs.) **<=** 0.900.
The sample will get EQUIVOCAL remarks having INDEX Value,
(Sam. Abs./ Cutoff Abs.) in the range from 0.900 to 1.000.

S. To save the test after entering all the parameters, select option 'SAVE'.

Name: HBSAG POS- Cut Off
Pri: 450 Sec: 630 ESC

	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				

CUTFAC: 0.200
CUTABS: NC + PC + CF
QC1 > Y 0.500 Interpretation :
QC2N Greyzone % (Y) 10.00
QC3N Cut off Index (N)
QC4N Range

User Manual

T. Example Print-out obtained from ELISA Plate Analyser

POS-CutOff

Name : HCV
Pri : 450 Sec : 630

	NO	Factor	QC	QCVal	Meas.
BL	1		Y	0.100	
NC	2	0.000	Y	0.150	0.000
PC	2	0.100	Y	0.500	0.000
LC	0	1.000	N		
CC	0	1.000	N		

CUTFAC : 0.100
CUTABS : .1*PC+CF

QC1	N	Interpretation :	
QC2	N	Greyzone%(Y)	10.0
QC3	N	Cutoff Range	Index (N)
QC4	N		

HCV, 21/07/08

A

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
B	S4	S12	S20	S28	S36	S44	S52	S60	S68	S76	S84
	OPD13	OPD21	OPD29	OPD37	OPD45	OPD53	OPD61	OPD69	OPD77	OPD85	OPD93
0.002	0.147	0.091	0.011	0.083	0.127	0.362	0.072	0.400	1.454	0.743	0.222
0.000	1.302	0.803	0.099	0.737	1.122	3.201	0.636	3.533	12.84	6.564	1.959
	POS	NEG	NEG	NEG	POS	POS	NEG	POS	POS	POS	POS

B

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S5	S13	S21	S29	S37	S45	S53	S61	S69	S77	S85
	OPD14	OPD22	OPD30	OPD38	OPD46	OPD54	OPD62	OPD70	OPD78	OPD86	OPD94
0.062	0.145	0.382	2.535	0.116	1.470	2.573	0.115	2.515	0.747	0.748	0.003
0.000	1.278	3.372	22.39	1.024	12.99	22.73	1.011	22.22	6.597	6.608	0.025
	POS	POS	POS	EQ	POS	POS	EQ	POS	POS	POS	NEG

C

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S6	S14	S22	S30	S38	S46	S54	S62	S70	S78	S86
	OPD15	OPD23	OPD31	OPD39	OPD47	OPD55	OPD63	OPD71	OPD79	OPD87	OPD95
0.040	2.573	0.129	0.159	0.133	0.217	0.077	0.091	1.584	1.557	0.502	2.638
0.000	22.72	1.136	1.405	1.177	1.917	0.677	0.804	13.99	13.75	4.434	23.30
	POS	POS	POS	POS	POS	NEG	NEG	POS	POS	POS	POS

D

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
PC	S7	S15	S23	S31	S39	S47	S55	S63	S71	S79	S87
	OPD16	OPD24	OPD32	OPD40	OPD48	OPD56	OPD64	OPD72	OPD80	OPD88	OPD96
0.080	0.157	2.630	0.141	2.642	0.058	0.155	0.159	1.515	0.071	0.423	0.209
0.000	1.389	23.23	1.246	23.33	0.516	1.370	1.403	13.38	0.628	3.732	1.850
	POS	POS	POS	POS	NEG	POS	POS	POS	NEG	POS	POS

E

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
PC	S8	S16	S24	S32	S40	S48	S56	S64	S72	S80	S88
	OPD17	OPD25	OPD33	OPD41	OPD49	OPD57	OPD65	OPD73	OPD81	OPD89	OPD97
2.562	0.172	0.198	0.061	0.182	0.165	2.656	0.156	0.080	2.616	0.259	0.224
0.000	1.517	1.751	0.536	1.612	1.457	23.46	1.377	0.705	23.11	2.291	1.978
	POS	POS	NEG	POS	POS	POS	POS	NEG	POS	POS	POS

F

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S1	S9	S17	S25	S33	S41	S49	S57	S65	S73	S81	S89
OPD10	OPD18	OPD26	OPD34	OPD42	OPD50	OPD58	OPD66	OPD74	OPD82	OPD90	OPD98
2.626	2.612	0.055	0.116	2.649	0.188	0.176	0.052	2.638	0.855	0.899	0.419
23.19	23.07	0.483	1.023	23.40	1.660	1.553	0.460	23.30	7.548	7.942	3.699
POS	POS	NEG	EQ	POS	POS	POS	NEG	POS	POS	POS	POS

G

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S2	S10	S18	S26	S34	S42	S50	S58	S66	S74	S82	S90
OPD11	OPD19	OPD27	OPD35	OPD43	OPD51	OPD59	OPD67	OPD75	OPD83	OPD91	OPD99
0.049	0.140	2.595	0.138	0.142	0.117	2.611	0.076	0.081	0.050	0.403	2.579
0.429	1.234	22.92	1.215	1.252	1.035	23.06	0.672	0.717	0.441	3.564	22.78
NEG	POS	POS	POS	POS	EQ	POS	NEG	NEG	NEG	POS	POS

H

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S3	S11	S19	S27	S35	S43	S51	S59	S67	S75	S83	S91
OPD12	OPD20	OPD28	OPD36	OPD44	OPD52	OPD60	OPD68	OPD76	OPD84	OPD92	OPD100
0.061	0.109	0.002	0.071	0.076	0.131	0.109	0.101	0.082	2.560	0.399	0.015
0.538	0.964	0.018	0.631	0.670	1.157	0.960	1.896	0.721	22.61	3.527	0.132
NEG	EQ	NEG	NEG	NEG	POS	EQ	NEG	NEG	POS	POS	NEG

User Manual

8.4. Reverse Cut Off Mode

For Reverse Cut Off mode, select touch zone ‘POS’- Cut off key. It will change to REV- Cut Off.

Name: REV- CutOff
Pri: 450 Sec: 0 ESC
No

	Factor	QC	QCVal	Mes.	Rem	SAVE
BL 0		N				
NC 0	1.000	N				
PC 0	1.000	N				
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.000
CUTABS:
QC1N Interpretation :
QC2N Greyzone % (Y) 10.00
QC3N Cut off Index (N)
QC4N Range

In Reverse Cut Off Mode, programming of test is the same as Positive Cut off Mode. Only QC check conditions for blanks and controls get reversed. In the ‘INTERPRETATION’, sample absorbance, which is lesser than cut off absorbance, gets remarked POSITIVE . Sample absorbance higher than cut off absorbance, gets remarked NEGATIVE. This is exactly the opposite to normal POSITIVE Cut Off Mode. Same way in case you select ‘Cutoff Index Range’.

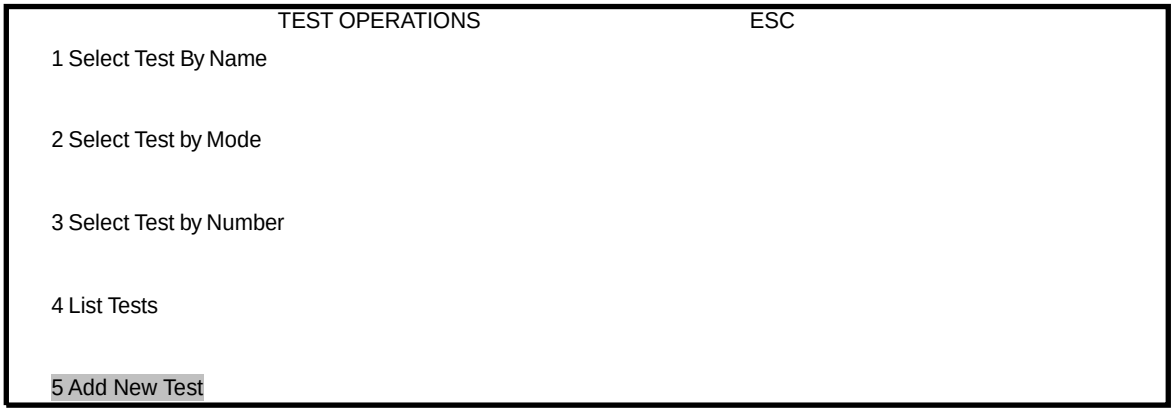
8.5. Multi Standard Mode:

In this mode the instrument accepts a maximum of 12 calibrators and calculates concentration based on the best-fit curve. Graph is printed with Absorbance on Y-axis and concentration on X-axis.

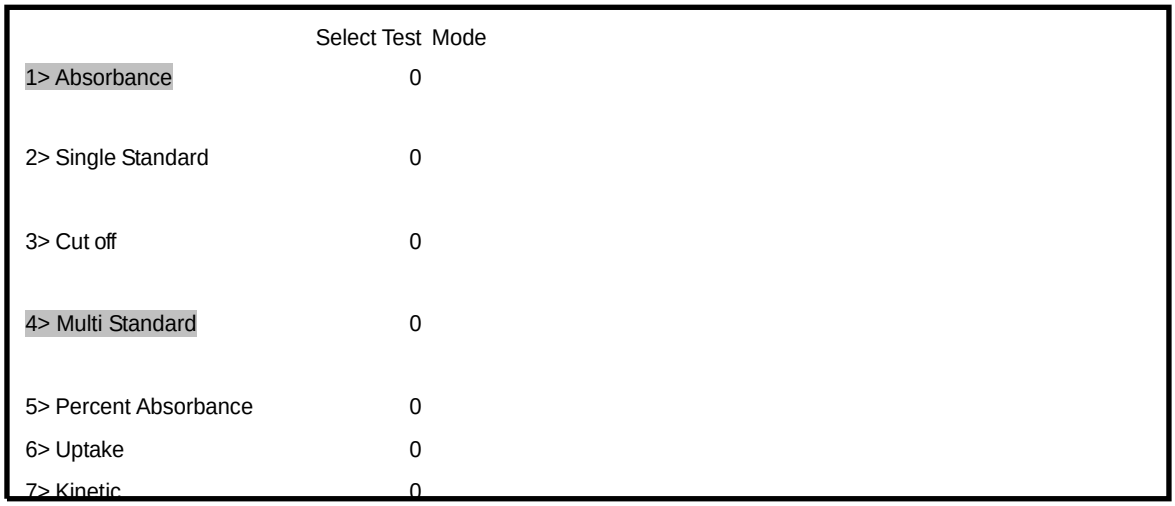
User Manual

Programming a New Test:

A.Select Main Menu/Test Operation/Add New Test

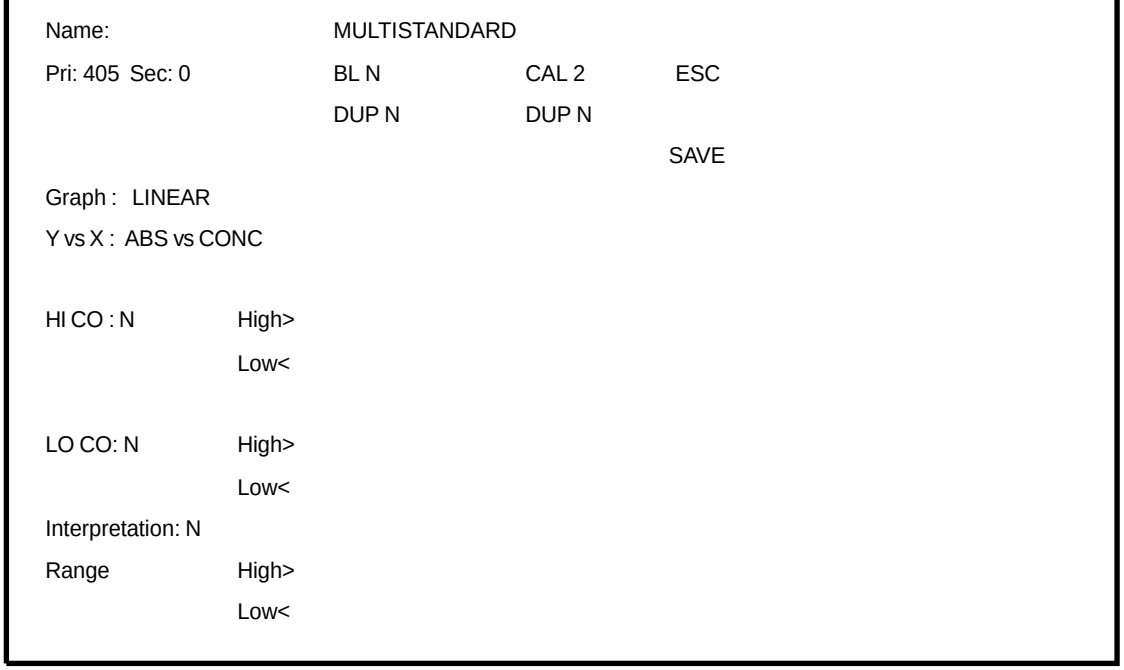


B. Select Touch Zone "Multi Standard"



User Manual

After selecting the Multistandard mode below screen will come on the display



C. Entry of Test Name

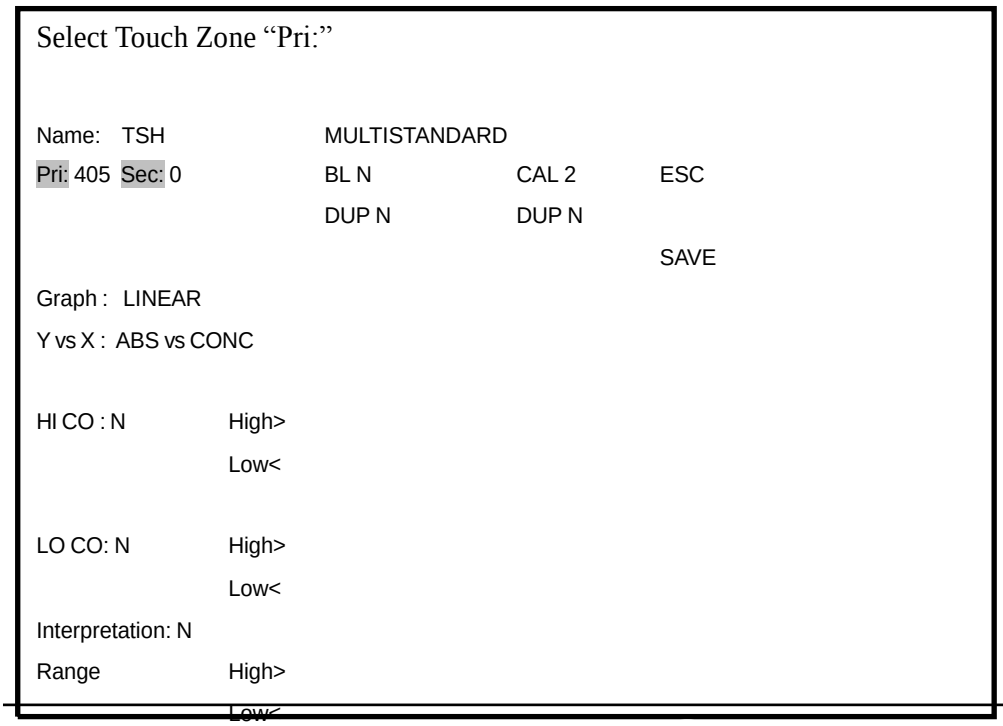
Test Name can be entered by Selecting Touch Zone “Name:”.

Procedure for entering the test name is the same as the one of cut off mode.

Refer Test Name entry in Cut off mode for further details.

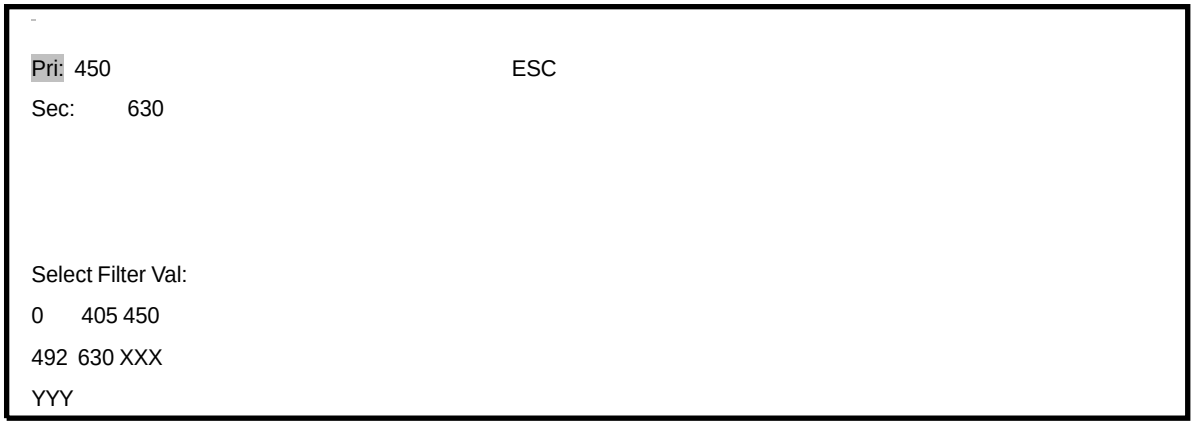
D. Selection of Primary and secondary filters

Select Touch Zone “Pri:”



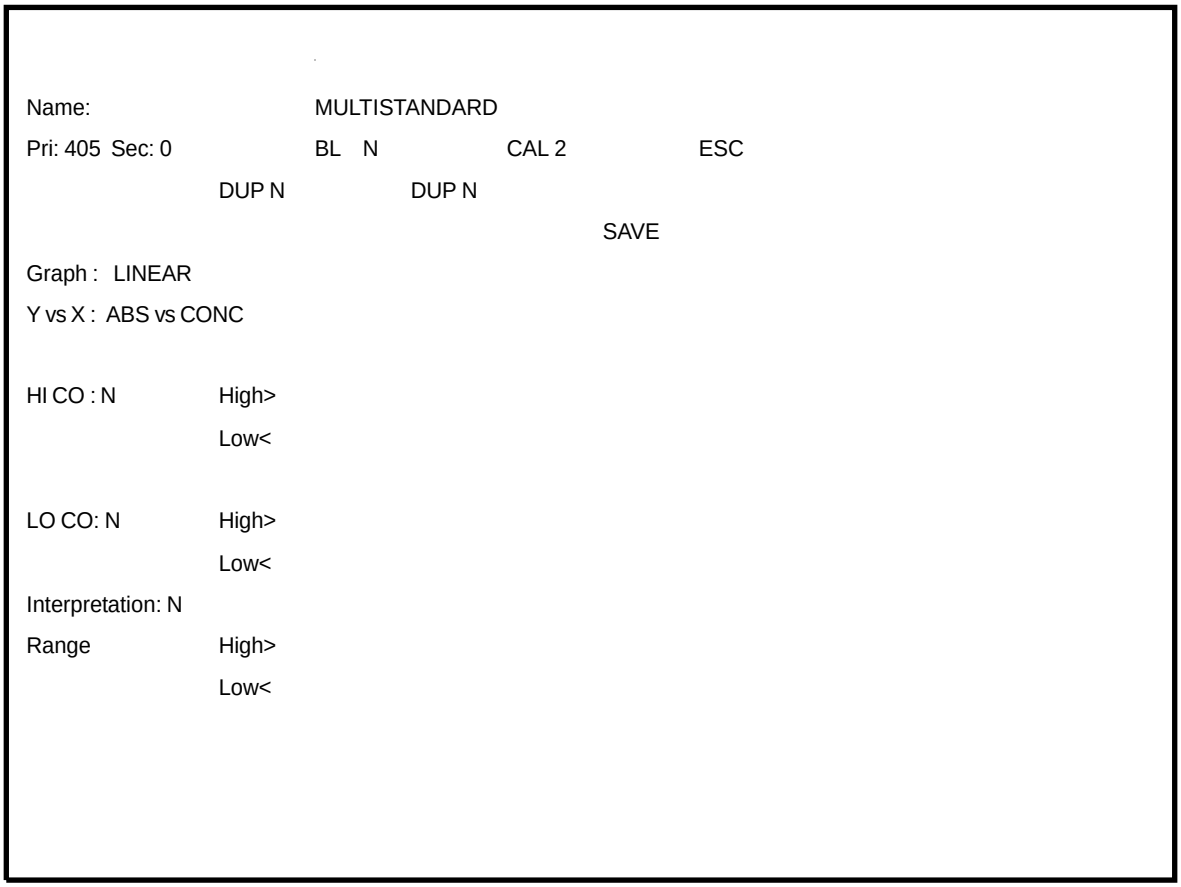
After selecting the Zone "Pri:" below screen will come on the display

Select the filters as per details given in the reagent manual by selecting the filter number given in the "Select Filter value:" option.



E. Selection of Blank

Select Touch Zone "BL"



Instrument will display the message "Blank required Yes/No". At the bottom of the Screen as shown below, select yes if blank is required

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL N CAL 2 ESC
DUP N DUP N
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

HI CO : N High>
Low<

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<
YES
Blank Required ?
NO

F. Entry of Standard Concentration

Select touch Zone "CAL" to enter Number of calibrators and its concentration.

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL N 0.000 CAL 2 ESC
DUP N DUP N
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

HI CO : N High>
Low<

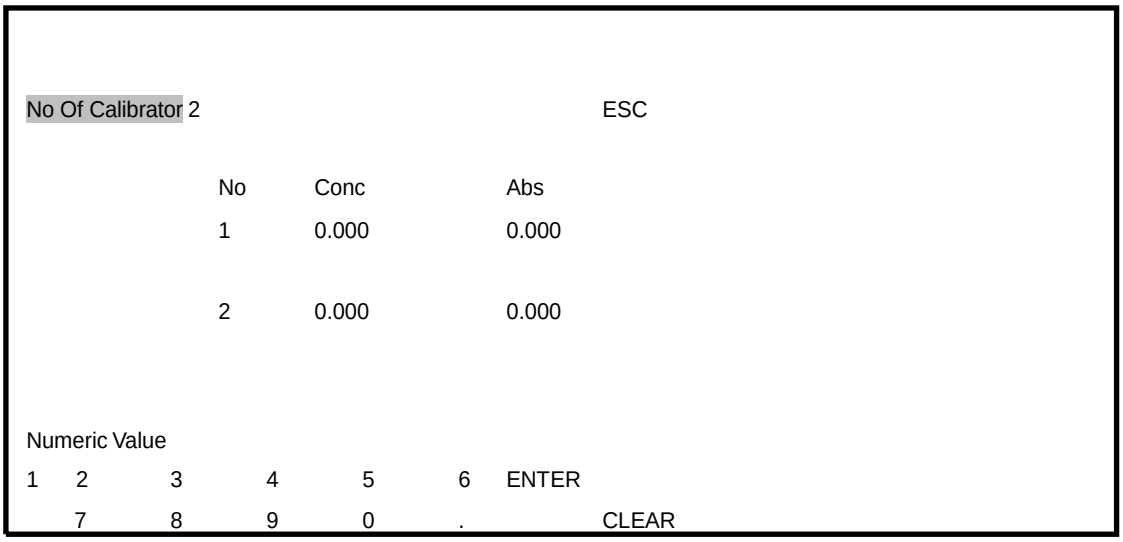
LO CO: N High>
Low<
Interpretation: N
Range High>
Low<

User Manual

After selecting “CAL” the following screen will appear on the display:

Select Touch Zone “No. Of Calibrators”. Numerals will display on the bottom of the screen.

Select the number of calibrators (User can select min 2 and max. 12 standard in this mode).

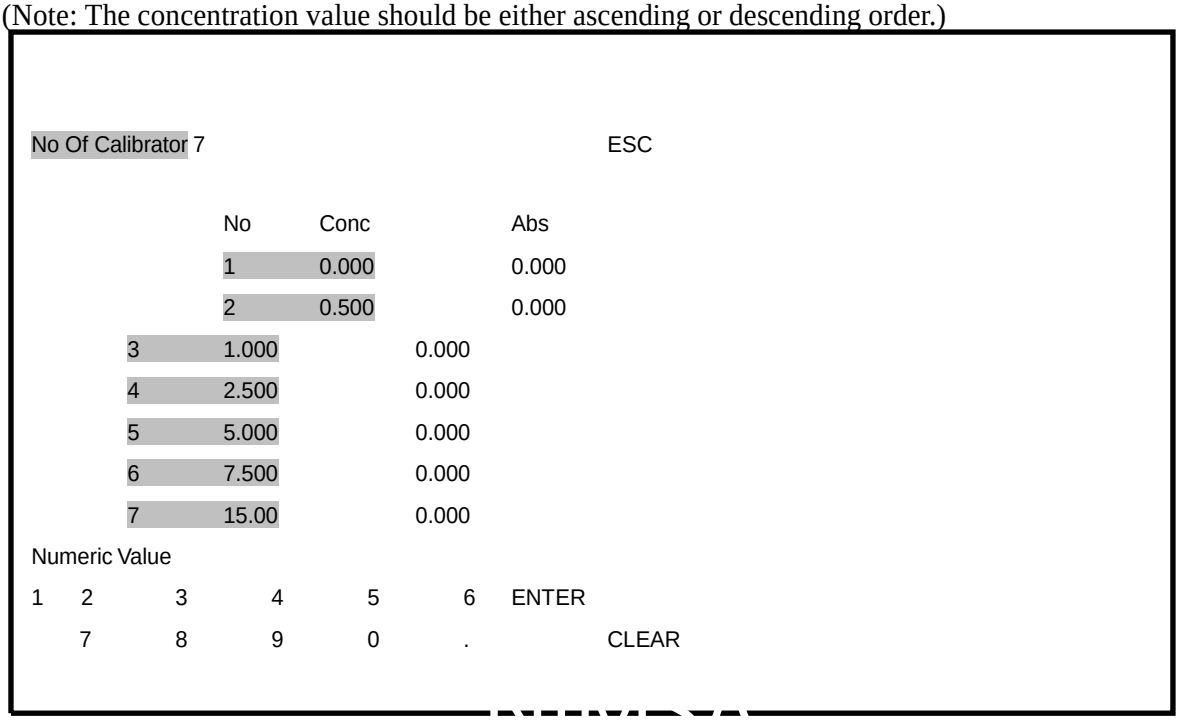


Concentration Entry:

After entering the number of calibrators, concentration and absorbance column will come on the display as shown below.

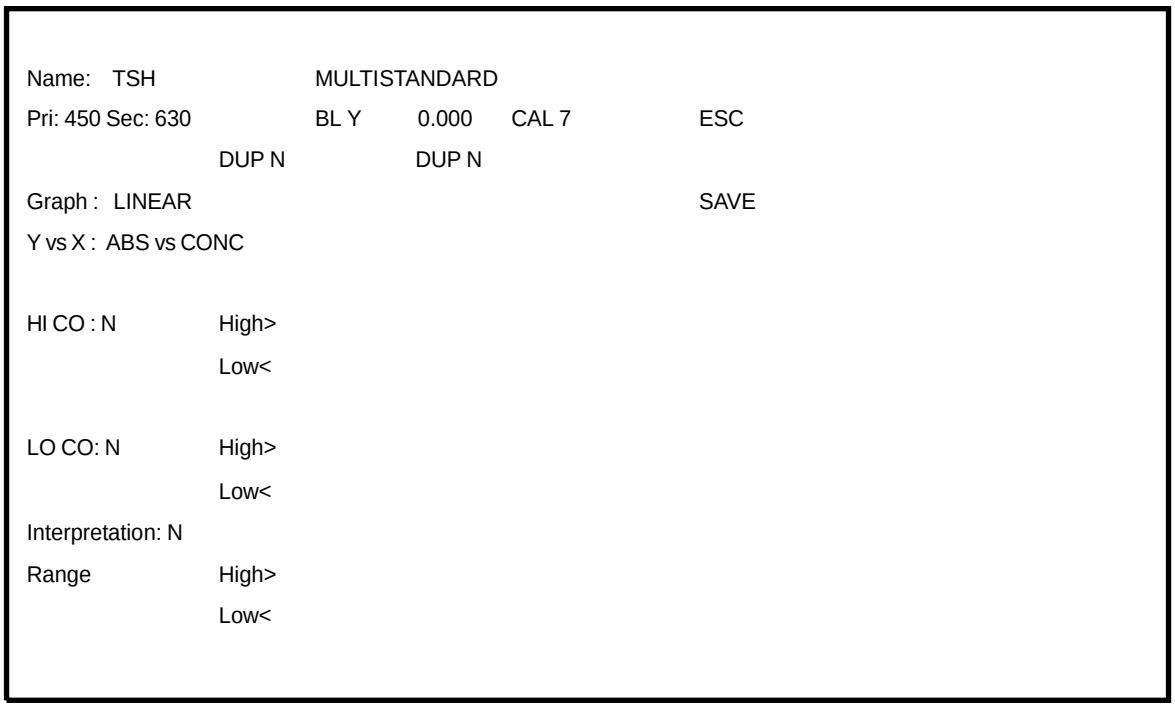
To enter concentration values select 0.000 in Conc. column corresponding to the standard and enter the concentration value. e.g. for entering Concentration of standard 4 Select 0.000 in fourth row of Conc. Column and enter the concentration by selecting the numerals.

(Note: The concentration value should be either ascending or descending order.)



User Manual

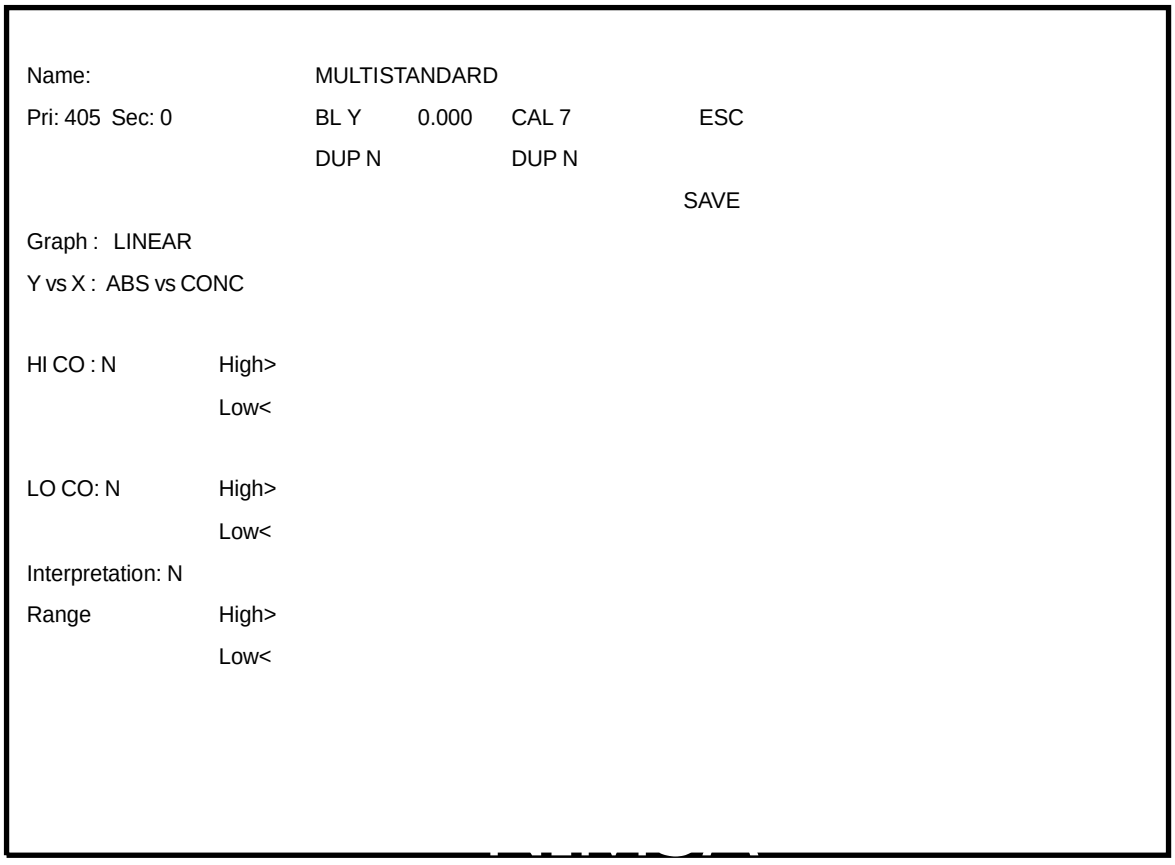
Programming Screen after Entry of standards.



G. Selection of Duplicate Blank and calibrators

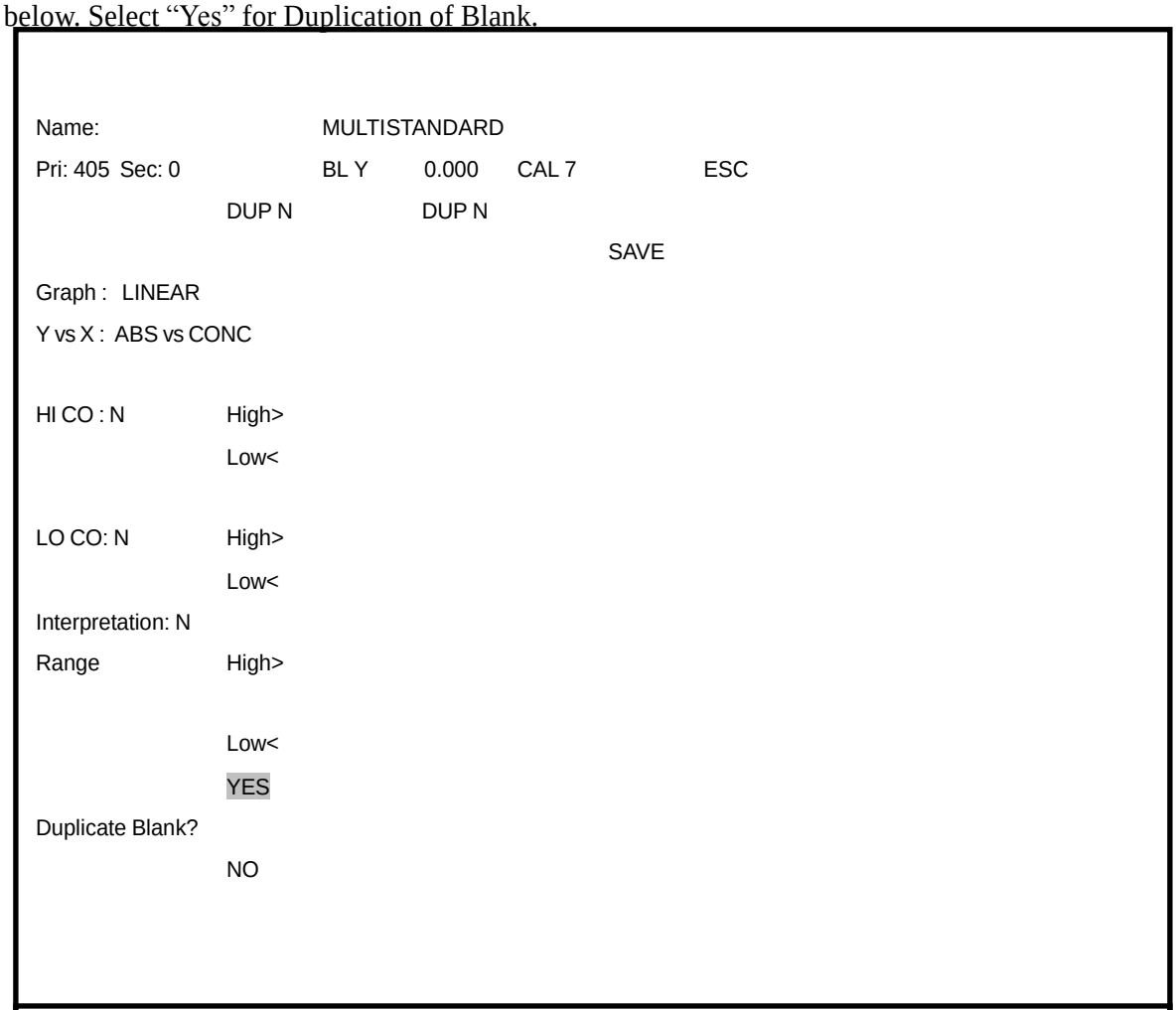
For Duplicate Blank:

Select touch zone “DUP” below the “BLN”



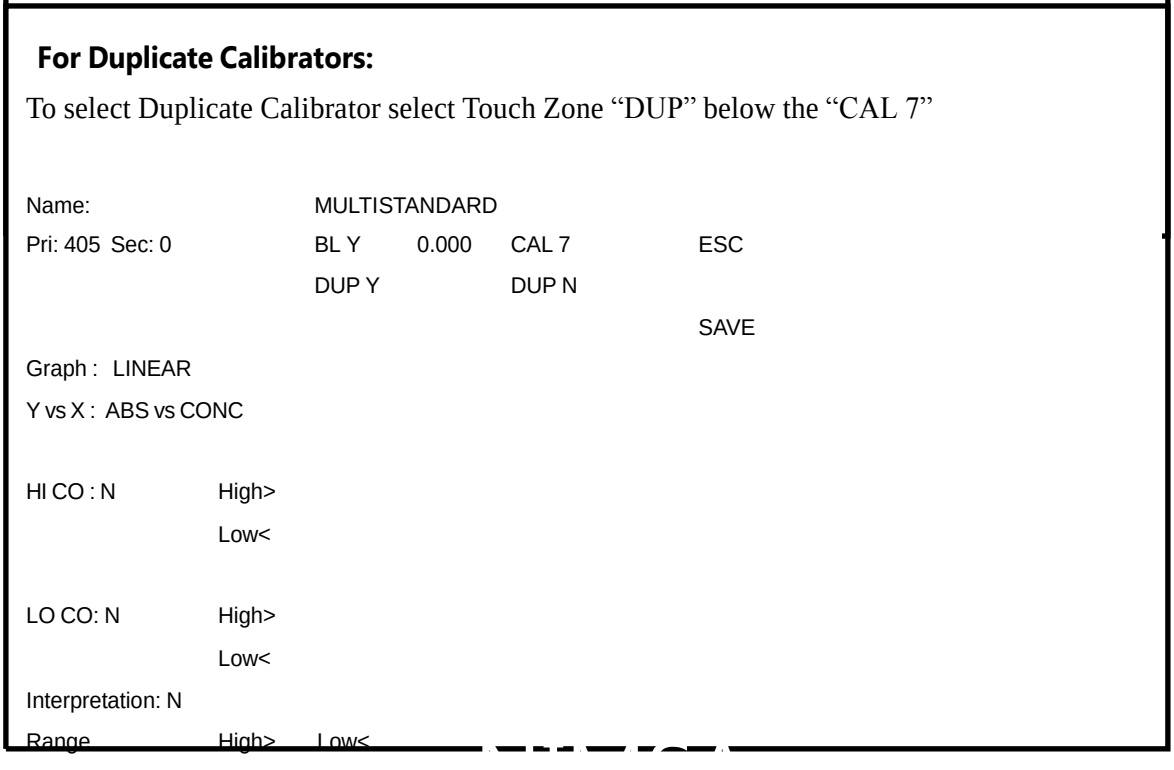
User Manual

After selecting "DUP" instrument will display message "Duplicate Blank Yes/No" as shown below. Select "Yes" for Duplication of Blank.



For Duplicate Calibrators:

To select Duplicate Calibrator select Touch Zone "DUP" below the "CAL 7"



User Manual

After selecting "DUP" instrument will display message "Duplicate Calibrator Yes/No" as shown below. Select "Yes" for Duplication of calibrator.

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL Y 0.000 CAL 7 ESC
DUP Y DUP N
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

HI CO : N High>
Low<

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<
YES
Duplicate Calibrator?
NO

Screen after standard entry & selection of duplicate – Blank & Calibrators.

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL Y 0.000 CAL 7 ESC
DUP Y DUP Y
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

HI CO : N High>
Low<

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<

H) Linear mode and Point to Point mode

There are two types of graphs in Multistandard

Linear (LINEAR)

Point to Point (PT TO PT)

There are five types of scales for X and Y axis

LOGABS vs CONC (X-axis = Concentration v/s Y-axis = LOG of ABS.)

ABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = Absorbance)

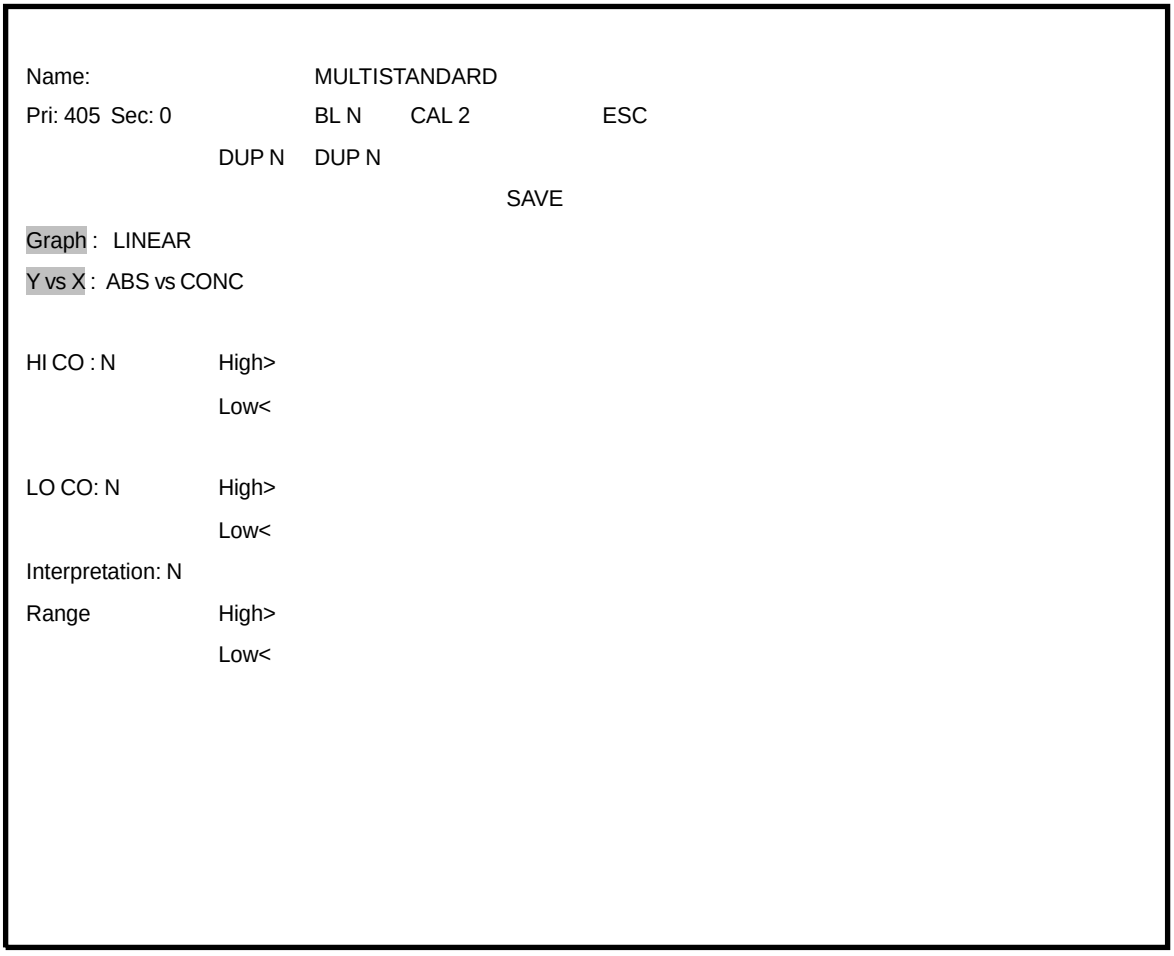
LOGITABS VS LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOGIT of Absorbance)

ABS vs CONC (X-axis = Concentration v/s Y-axis = Absorbance)

LOGABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOG of absorbance)

Selection of Graph

Select Graph type as per the details given in the reagent manual by selecting Touch Zone “Graph”.

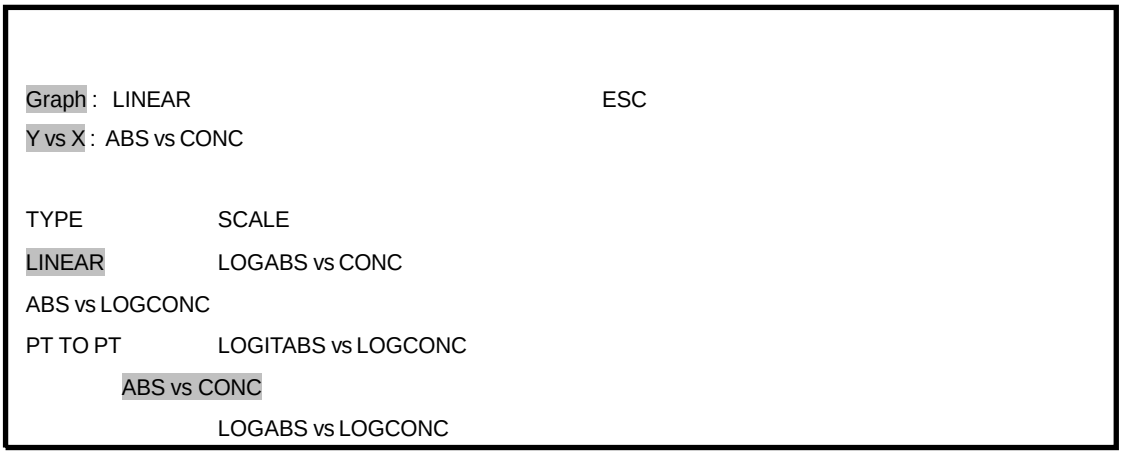


Linear mode graph type:

After Selecting the “Graph” follow screen will come on the display.

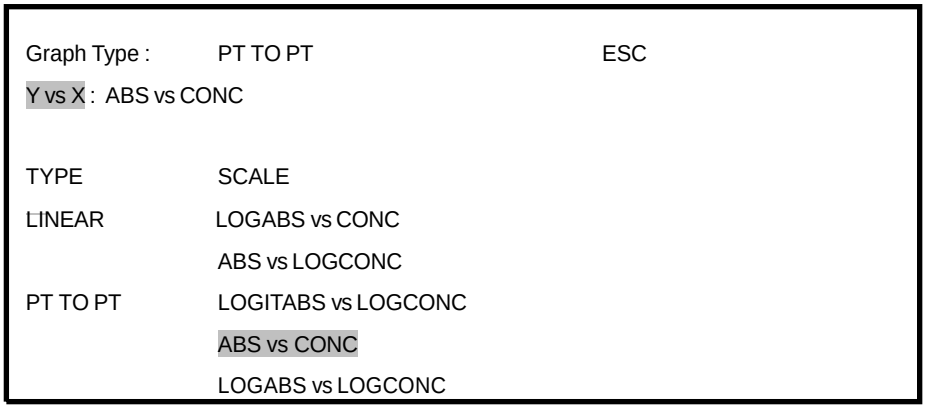
Select Graph type as Linear.

Select scale as per the details given in the reagent manual.



Point to Point Graph Type:

Select touch zone “PT to PT” abs scale of graph ‘ABS vs. CONC’.



User Manual

Select the scale type touching the required zone.

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL N CAL 2 ESC
DUP N DUP N
SAVE
Graph : PT TO PT
Y vs X : ABS vs CONC

HI CO : N High>
Low<

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<

I. Selection of Controls

For High control select zone ‘HI CO: N’ Following message appears: “High Control Required? Yes / No”. Select ‘YES’ and then enter range of control “HIGH” and “LOW”.

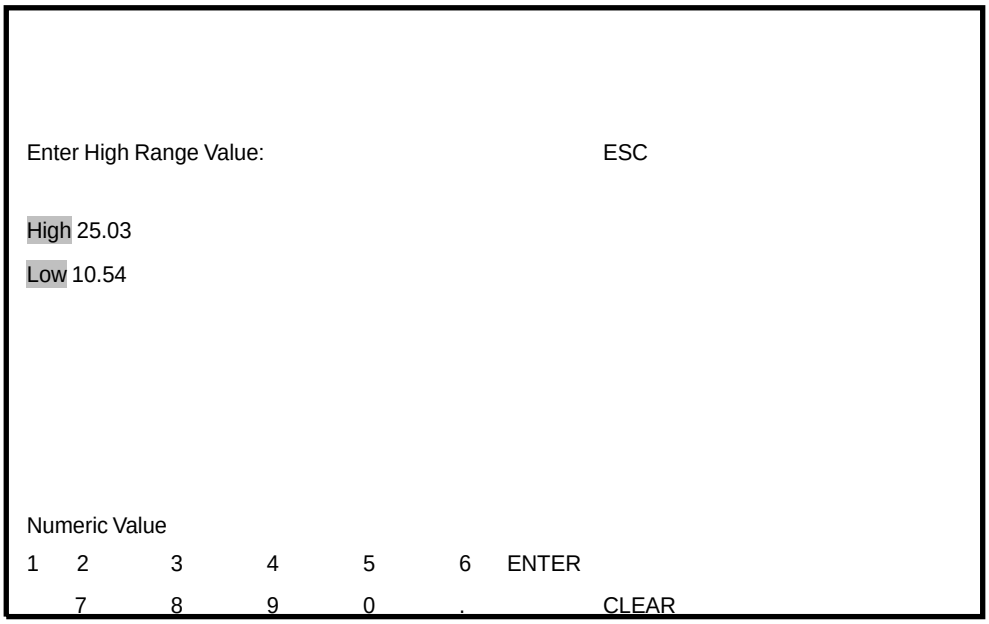
Name: MULTISTANDARD
Pri: 405 Sec: 0 BL N CAL 2 ESC
DUP N DUP N
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

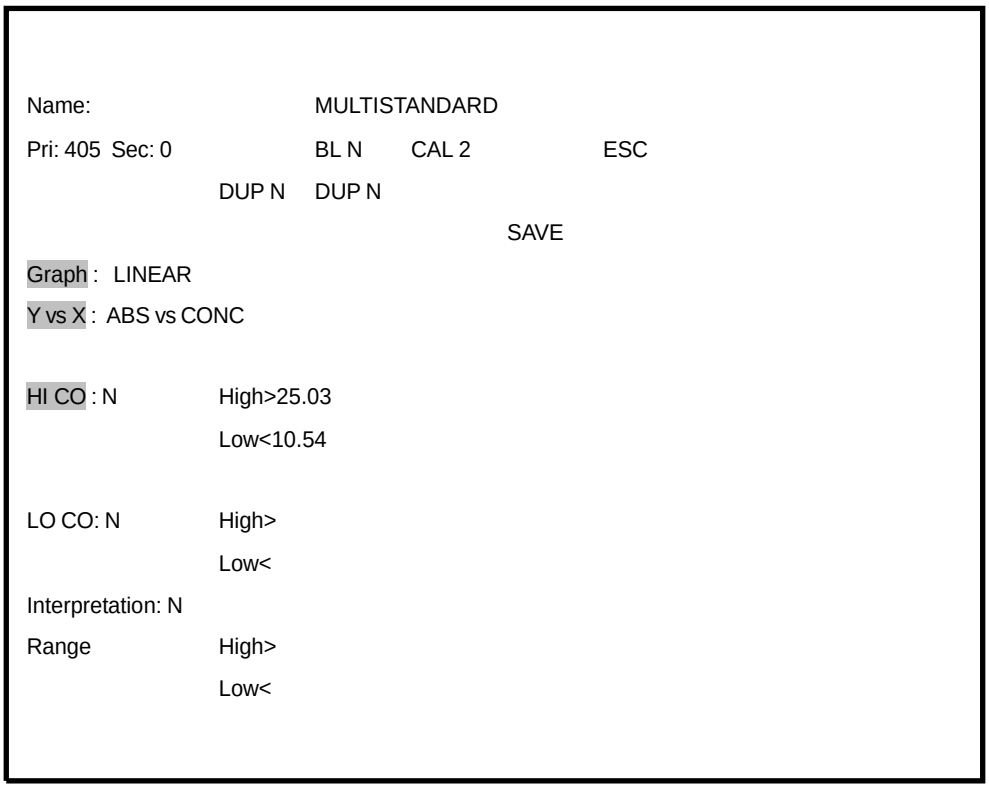
HI CO : N High>
Low<

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<
YES
High Control Required?
NO

User Manual

Enter range of control "HIGH" and "LOW" as per reagent manual.





User Manual

For Low control select zone 'LO CO: N' It will ask "Low Control Required? Yes / No".

Select 'YES'

Name: MULTISTANDARD
Pri: 405 Sec: 0 BL N CAL 2 ESC
DUP N DUP N
SAVE
Graph : LINEAR
Y vs X : ABS vs CONC

HI CO : N High>25.03
Low<10.54

LO CO: N High>
Low<
Interpretation: N
Range High>
Low<
YES
Low Control Required?
NO

Enter the range 'High' and 'Low' as per the reagent manual.

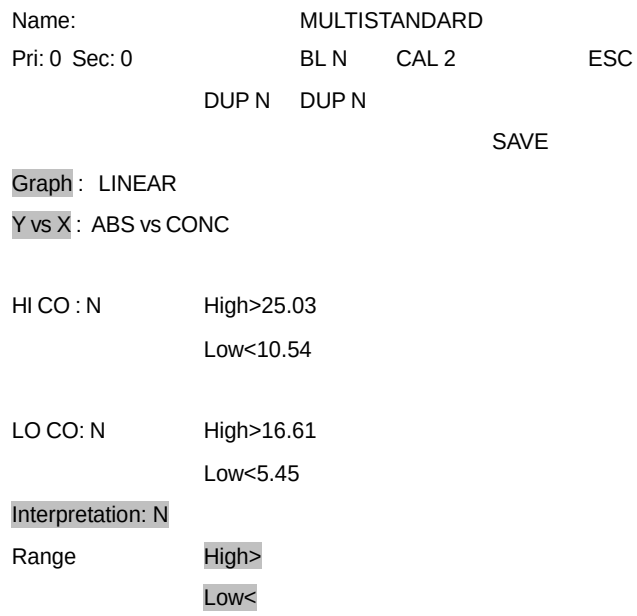
High> 16.61 ESC
Low< 5.45

Numeric Value
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR

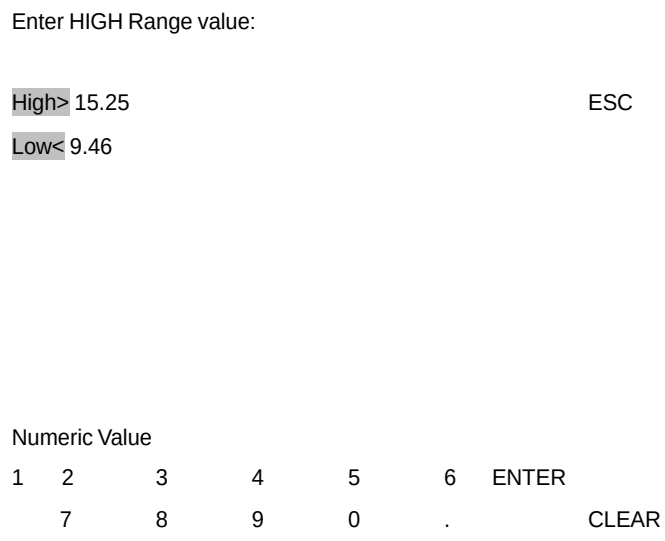
User Manual

J. Normal Range selection for interpretation of samples:

For interpretation of specimen result (POSITIVE or NEGATIVE), enter normal range given in REAGENT MANUAL. Select key “Interpretation: N”. It will become “Interpretation: Y”. Then select key “HIGH>” and “LOW<” to enter normal range.



Enter Normal Range for positive and negative samples.



All the results whose concentration is coming above the High Range will be considered as positive and coming below the Low Range will be consider as negative. The results having concentration in between High and Low range will get remarks ‘Equivocal’ = ‘EQ’.

User Manual

After entering all the parameters save the test by selecting "SAVE" option.

Name: TSH MULTISTANDARD

Pri: 450 Sec: 630 BL Y 0.000 CAL 7 ESC

DUP N DUP N

SAVE

Graph : LINEAR

Y vs. X : ABS vs CONC

HI CO : N High>25.03

Low<10.54

LO CO: N High>16.61

Low<5.45

Interpretation: Y

Range High> 15.25

Low< 9.46

(*Same way you can make a test for Single standard, % Absorbance and uptake)

User Manual

J. Example Print-out obtained

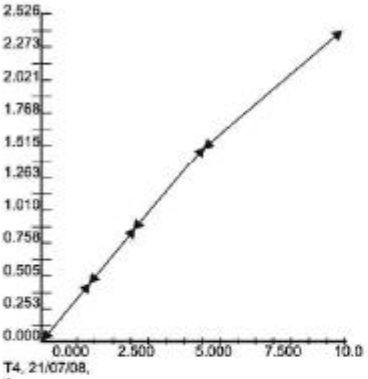
MULTI STDS

Name : T4
Pri : 450 Sec : 630

BL	N	DUP	N	
CAL	5	DUP	Y	
Graph :		PT	TO	PT
Y vs X :		ABS	vs	CONC
HI	CO : N	High >		
		Low<		
LO	CO : N	High>		
		Low<		
Range	Y	High>	6.000	
		Low<	4.000	

No	Con	Abs
1	0.000	0.000
2	1.500	0.000
3	2.500	0.000
4	4.500	0.000
5	10.00	0.000

Origin at : x = 0.000, y = 0.000
x / div = 0.625, y / div = 0.126



T4, 21/07/08,

A

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C1	C5	S4	S8	S12	S16	S20	S24	S28	S32	S36	S40
		OP33	OP37	OP41	OP45	OP49	OP53	OP57	OP61	OP65	OP69
0.004	2.568	0.711	0.728	0.796	0.423	0.744	0.728	0.768	0.141	0.700	0.151
0.000	10.00	3.175	3.226	3.275	1.880	2.203	2.240	2.255	0.527	2.141	0.475
		NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

B

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C	C	S	S	S	S	S	S	S	S	S	S
0.017	2.485	1.432	1.448	1.412	0.755	0.709	0.756	0.729	0.173	0.700	0.134
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

C

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C2	S1	S5	S9	S13	S17	S21	S25	S29	S33	S37	S41
	OP30	OP34	OP38	OP42	OP46	OP50	OP54	OP58	OP62	OP66	OP70
0.413	2.603	0.081	0.801	0.154	0.448	0.155	0.161	2.547	0.766	0.854	2.625
1.500	10.43	0.273	2.382	0.516	1.963	0.523	0.533	10.30	2.340	2.444	10.43
	POS	NEG	NEG	NEG	NEG	NEG	NEG	POS	NEG	NEG	POS

D

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C	S	S	S	S	S	S	S	S	S	S	S
0.442	2.609	0.092	0.804	0.153	0.800	0.156	0.157	2.615	0.803	0.803	2.589
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

E

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C3	S2	S6	S10	S14	S18	S22	S26	S30	S34	S38	S42
	OP31	OP35	OP39	OP43	OP47	OP51	OP55	OP59	OP63	OP67	Op71
0.823	1.520	0.155	0.846	0.154	2.616	0.531	0.454	0.448	2.366	1.542	1.431
2.500	4.772	0.532	2.600	0.532	7.579	1.547	1.487	1.539	11.15	4.738	4.386
	EQ	NEG	NEG	NEG	POS	NEG	NEG	NEG	POS	EQ	EQ

F

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C	S	S	S	S	S	S	S	S	S	S	S
0.882	1.584	0.161	0.924	0.162	1.533	0.363	0.393	0.440	3.096	1.549	1.497
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

G

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C4	S3	S7	S11	S15	S19	S23	S27	S31	S35	S39	S43
	OP32	OP36	OP40	OP44	OP48	OP52	OP56	OP60	OP64	OP68	OP72
1.483	1.490	1.419	1.410	0.149	1.456	0.159	2.447	2.637	1.415	1.454	1.453
4.500	4.478	4.337	4.393	0.520	7.114	0.510	9.689	10.24	4.293	4.376	4.442
	EQ	EQ	EQ	NEG	POS	NEG	POS	POS	EQ	EQ	EQ

H

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C	S	S	S	S	S	S	S	S	S	S	S
1.539	1.498	1.478	1.524	0.161	2.520	0.146	2.489	2.503	1.453	1.468	1.511
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

User Manual

8.6. Percentage Absorbance

The Percentage Absorbance Mode requires one calibrator (read singly or duplicate). In this mode, calibrator is considered to have a concentration of 100%. The absorbance's of unknown samples are read and compared to the calibrator absorbance, and reported as % concentration of calibrator.

Name: TSH		% ABSORBANCE			
Pri: 450 Sec: 630		BL Y	0.000	CAL 1	ESC
	DUP N		DUP N		
				SAVE	
HI CO: N	High>				
	Low<				
LO CO: N	High>				
	Low<				
Interpretation: N					
Range	High>				
	Low<				

8.7. Uptake

In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.0.

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law

Sample Concentration = Calibrator Absorbance * Calibrator Concentration

Sample Absorbance

Name: TSH		UPTAKE			
Pri: 450 Sec: 630		BL Y	0.000	CAL 1	ESC
	DUP N		DUP N		
				SAVE	
HI CO: N	High>				
	Low<				
LO CO: N	High>				
	Low<				
Interpretation: N					
Range	High>				
	Low<				

User Manual

Please refer single standard for parameter entry.

8.8.Kinetic mode of Operation

To create a new test in "KINETIC" mode.

KINETIC

Name : KINETIC ESC

Pri : 405 Sec : 0 SAVE

Read Time : 8-15 sec.

Read Period : 15 sec.

"Read Time" is total read period of whole test. You need to enter it only in minutes.

"Read Period" is time interval between two readings. You must enter it in seconds. The instrument will automatically calculate the number of readings.

Select primary and secondary filters, give a name to test and save it.

To run the kinetic test.

KINETIC

Name : KINETIC ESC

Pri : 405 Sec : 0 EDIT

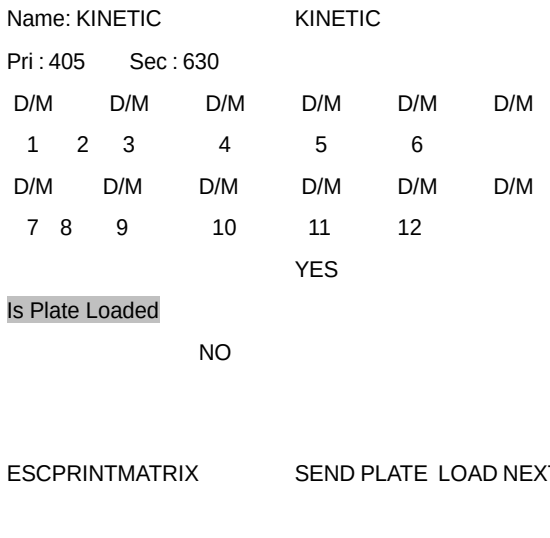
Read Time : 1 min. RUN

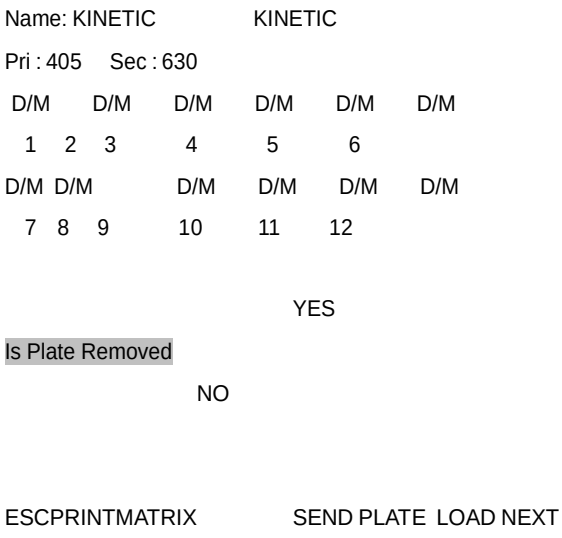
Read Period : 15 sec. PRINT

Select "RUN" to start.

User Manual

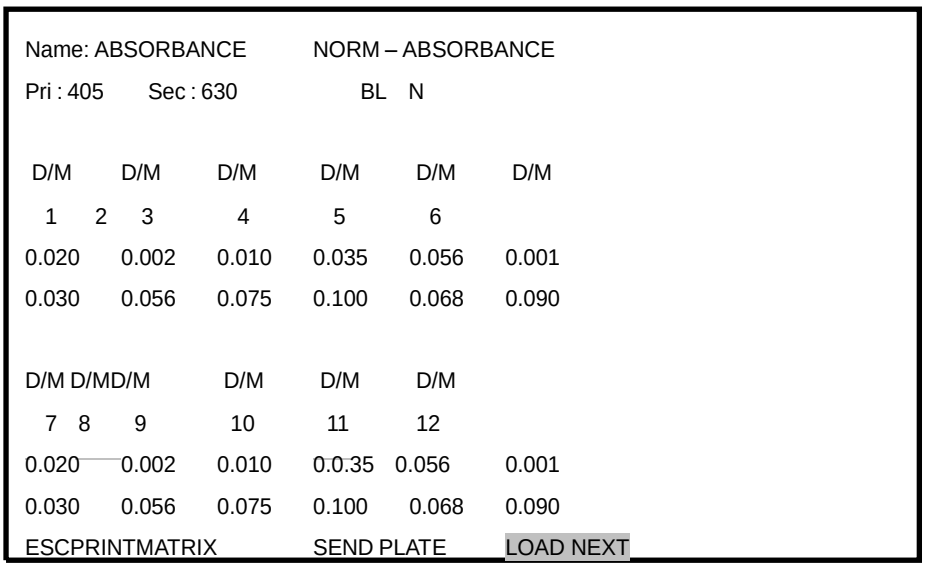
The "D/M" means delta per minute of reaction. When test will over, instrument will show you the "D/M" values of reaction done in each well.





User Manual

It is showing the "D/M" values for each and every well in table format.



In "PRINT MATRIX", you will get the print of entire plate data with initial absorbance of each sample, average delta values of each sample and "D/M" values of each well, like…

A

W1 W2 W3 W4 W5 W6

0.200 0.100 1.200 0.300 2.600 0.900.. these are initial absorbances.

0.010 0.001 0.005 0.017 0.028 0.001.. these are average delta values.

0.020 0.002 0.010 0.035 0.056 0.001.. these are "D/M" values of each sample.

B

W1 W2 W3 W4 W5 W6

0.300 0.100 1.200 0.200 2.600 0.800..

0.015 0.028 0.037 0.050 0.034 0.045..

0.030 0.056 0.075 0.100 0.068 0.090..

Using "SEND PLATE" you can send plate data to computer using either USB or SERIAL RS232.

"LOAD NEXT" uses to get the absorbance of next plate.

User Manual

KINETIC

Example Print-out obtained

Name : KIN_D

Pri : 450 Sec : 0

Read Time 1 min

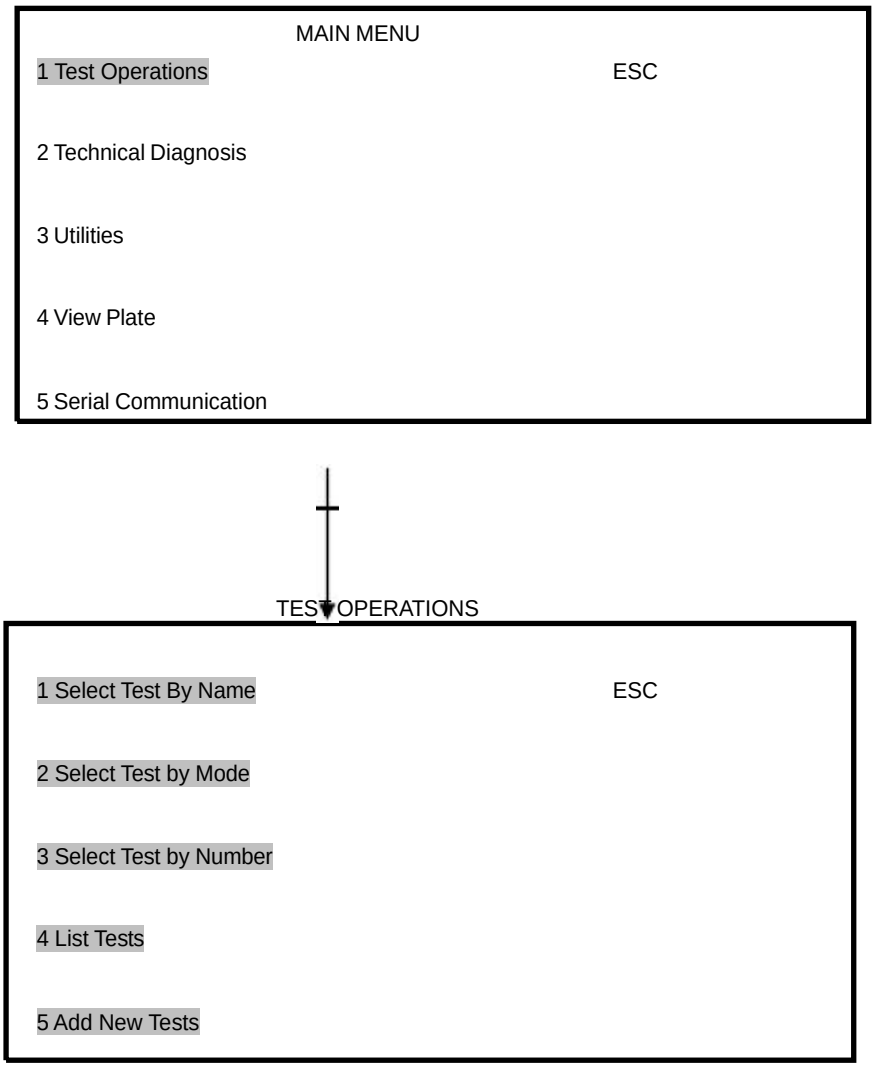
Read Period 15 sec

KIN_D, 21/07/08,

A											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.160	2.653	0.843	0.831	0.889	0.515	0.835	0.822	0.838	0.228	0.786	0.232
0.028	-0.004	-0.004	0.002	-0.002	-0.008	-0.008	0.020	0.017	-0.003	0.005	0.008
B											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.139	2.577	1.502	1.511	1.493	0.861	0.793	0.832	0.805	0.233	0.813	0.226
0.061	0.004	-0.002	0.020	0.026	0.023	0.011	-0.012	0.030	-0.004	0.022	0.015
C											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.502	2.700	0.168	0.878	0.278	0.523	0.236	0.252	2.592	0.867	0.963	2.720
0.042	0.001	0.004	0.011	0.014	0.014	0.029	0.037	0.005	0.030	0.009	0.018
D											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.536	2.730	0.196	0.897	0.260	0.897	0.257	0.255	2.720	0.907	0.912	2.698
0.015	0.014	0.027	0.013	0.035	0.043	0.027	0.012	-0.000	0.030	0.004	-0.016
E											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.936	1.608	0.264	0.938	0.282	2.711	0.635	0.556	0.568	2.462	1.655	1.542
0.036	0.024	0.021	0.027	-0.005	-0.008	-0.006	0.005	0.009	0.021	0.007	0.014
F											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
1.009	1.706	0.289	1.132	0.313	1.707	0.568	0.554	0.604	3.155	1.682	1.647
0.078	0.055	0.057	0.055	0.044	0.077	0.067	0.040	0.040	0.012	0.036	0.054
G											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
1.559	1.565	1.448	1.485	0.225	1.523	0.239	2.547	2.715	1.490	1.542	1.532
0.027	0.021	0.026	0.027	0.022	0.022	0.027	0.054	0.013	0.033	0.031	0.012
H											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
1.618	1.595	1.581	1.615	0.250	2.646	0.274	2.564	2.616	1.598	1.576	1.613
0.050	0.031	0.047	0.018	0.037	0.017	0.079	0.007	-0.020	0.050	0.022	0.003

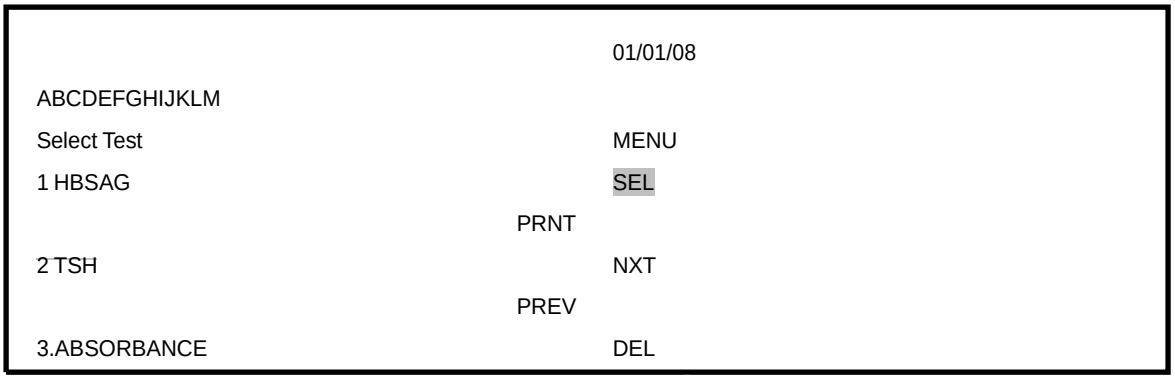
User Manual

9. RECALLING AND RUNNING OF STORED TEST/PROGRAMS



Test can be recalled by Name, Mode, Number or by List test.

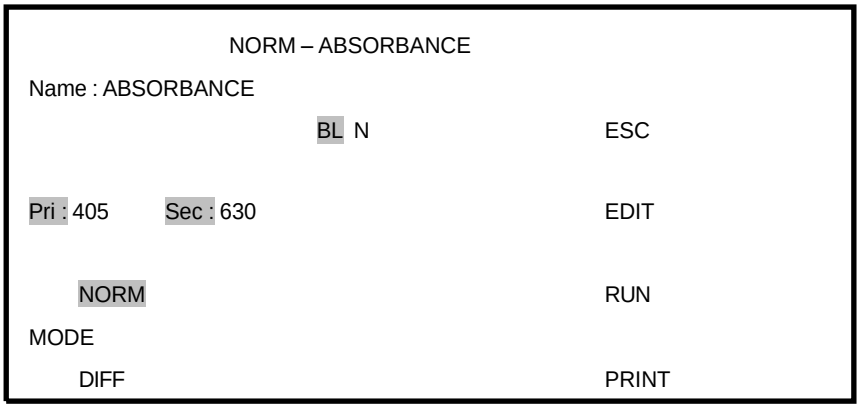
The entire saved tests are available on first screen, tests can be selected from this screen also.



User Manual

9.1. Absorbance Mode:

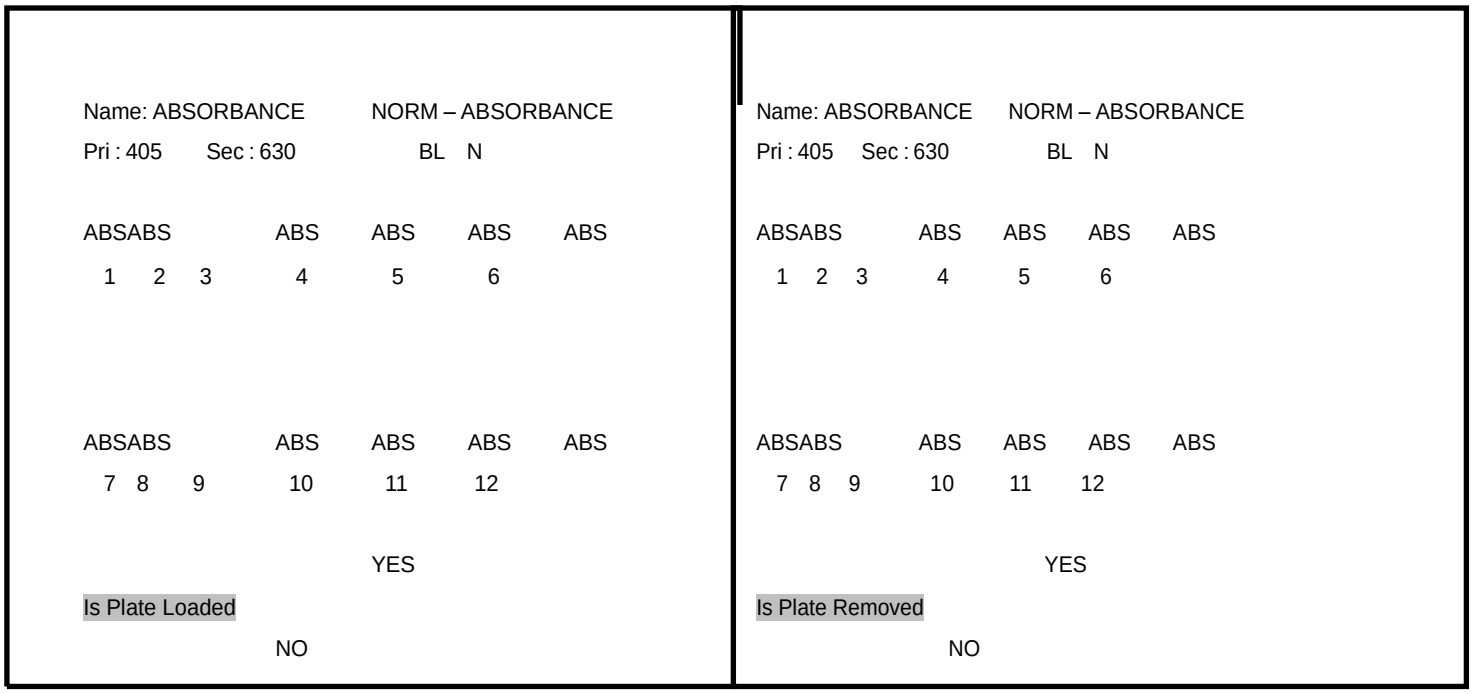
Select the test by “SEL” option.



Below screen will appear on the display after selecting the Run display.

The instrument will ask “Is Plate Loaded? YES / NO” Press Yes. Instrument will read the absorbances using mechanical plate movement. After completion of reading it will ask:

“**Is Plate Removed? YES / NO”. Remove the plate and Select YES**.



User Manual

Details of absorbances of all well in table format for each strip will display on the screen as shown below.

Name: ABSORBANCE NORM – ABSORBANCE
Pri : 405 Sec : 630 BL N

ABSABS		ABS	ABS	ABS	ABS
1	2 3	4	5	6	
0.125	0.250	0.350	0.450	0.550	0.650
-- --					
--					
--					
--					
0.125	0.250	0.350	0.450	0.550	0.650

ABSABS		ABS	ABS	ABS	ABS
7 8	9	10	11	12	
0.125	0.250	0.350	0.450	0.550	0.650

In this operation if you keep BLANK YES

The first well of first strip will be considered as blank and instrument will give the absorbances of remaining all well with blank subtraction from original absorbance.

The “PRINT MATRIX” will print the details of entire plate with well identification and absorbance of that well, like…..

A

W1	W2	W3	W4	W5	W6
0.125	0.250	0.350	0.450	0.550	o.650..

Using “SEND PLATE” plate data can be sent to computer using either USB or SERIAL RS232.

“LOAD NEXT” uses to get the absorbance of next plate.

Differential Absorbance Mode: In differential absorbance mode the instrument will give the absorbance difference each set of "ODD" number strip and EVEN number strip.

Name: ABSORBANCE NORM – ABSORBANCE
Pri : 405 Sec : 630 BL N

ABS 1	ABS 2	ABS 3	ABS 4	ABS 5	ABS 6
0.100			0.900		1.700
	0.200		1.000		1.800
	0.300		1.100		1.900
	0.400		1.200		2.000
	0.500		1.300		2.100
	0.600		1.400		2.200
	0.700		1.500		2.300
	0.800		1.600		2.400
ABS 7	ABS 8	ABS 9	ABS 10	ABS 11	ABS 12
0.100		0.900		1.700	
	0.200		1.000		1.800
	0.300		1.100		1.900
	0.400		1.200		2.000
	0.500		1.300		2.100
	0.600		1.400		2.200
	0.700		1.500		2.300
	0.800		1.600		2.400

ESC PRINTMATRIX SEND PLATE LOAD NEXT

It is showing the absorbances only for even number strips. This absorbance values are actually differences between each well of strip 1 and well of strip 2.You can get the difference between set of 1-2, 3-4, 5-6, 7-8, 9-10 and 11-12. It is not possible to change this combination.

In "PRINT MATRIX", you will get the print of entire plate data with actual absorbance of each well and difference of absorbance between ODD well and EVEN well, like

A

W1 W2 W3 W4 W5 W6 0.200 0.100 1.200 0.300 2.600 0.900..

0.000 0.100 0.000 0.900 0.000 1.700..

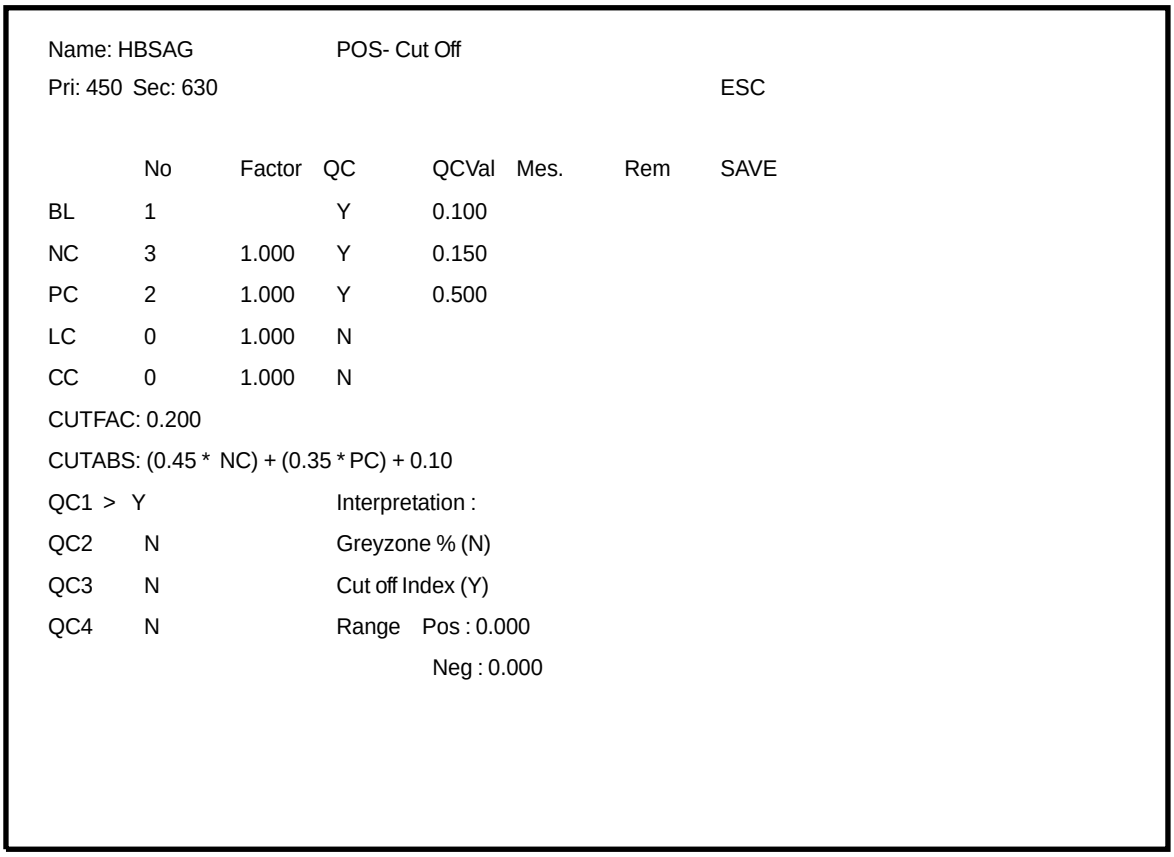
B

W1 W2 W3 W4 W5 W6 0.300 0.100 1.200 0.200 2.600 0.800..

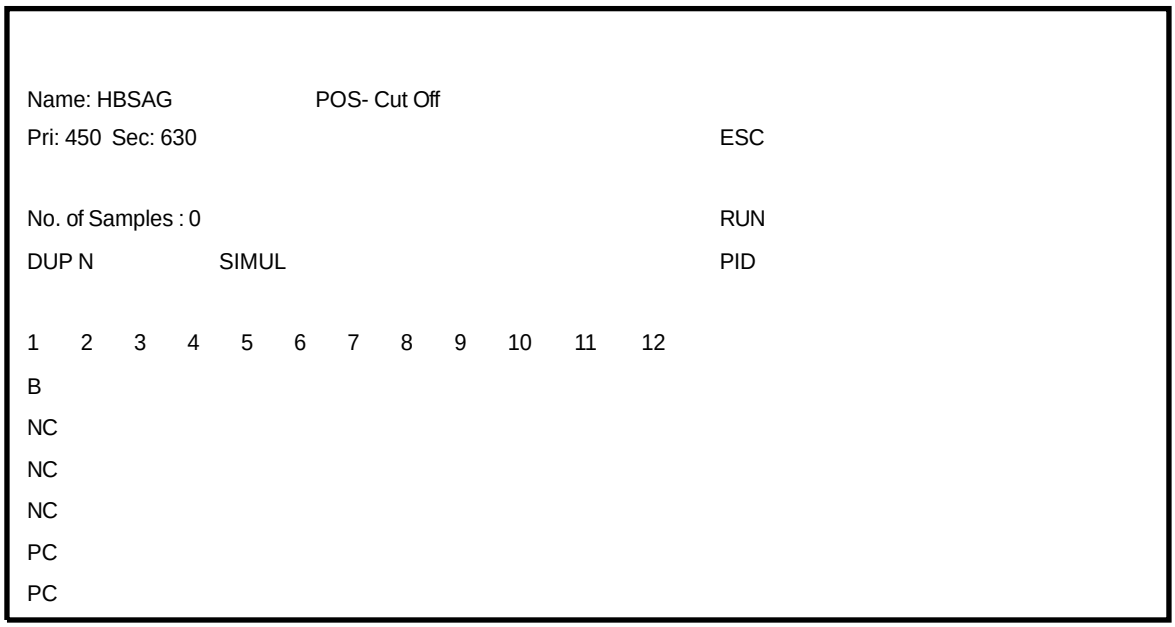
0.000 0.200 0.000 1.000 0.000 1.800..

User Manual

9.2.Cut off Mode



A) This test can be started by selecting RUN option. "PRINT" is used to print the details of test parameters.



B) It shows the 12 strips horizontal with 8 wells vertical with blanks and controls loaded in first strip. Enter theN°of samples by selecting that option and enter N° of samples you want to be loaded.

Name: HBSAG POS- Cut Off
Pri: 450 Sec: 630 ESC

No. of Samples : 10 RUN
DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12
B S3
NC S4
NC S5
NC S6
PC S7
PC S8
S1 S9
S2 S10

C) After entering N° of samples, press RUN. The plate-loading tray will come out and the following message will appear: "Is plate loaded? YES / NO".

Name: HBSAG POS- Cut Off
Pri: 450 Sec: 630 ESC

No. of Samples : 10 RUN
DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12
B S3
NC S4
NC S5
NC S6
PC S7
PC S8
S1 S9
S2 S10

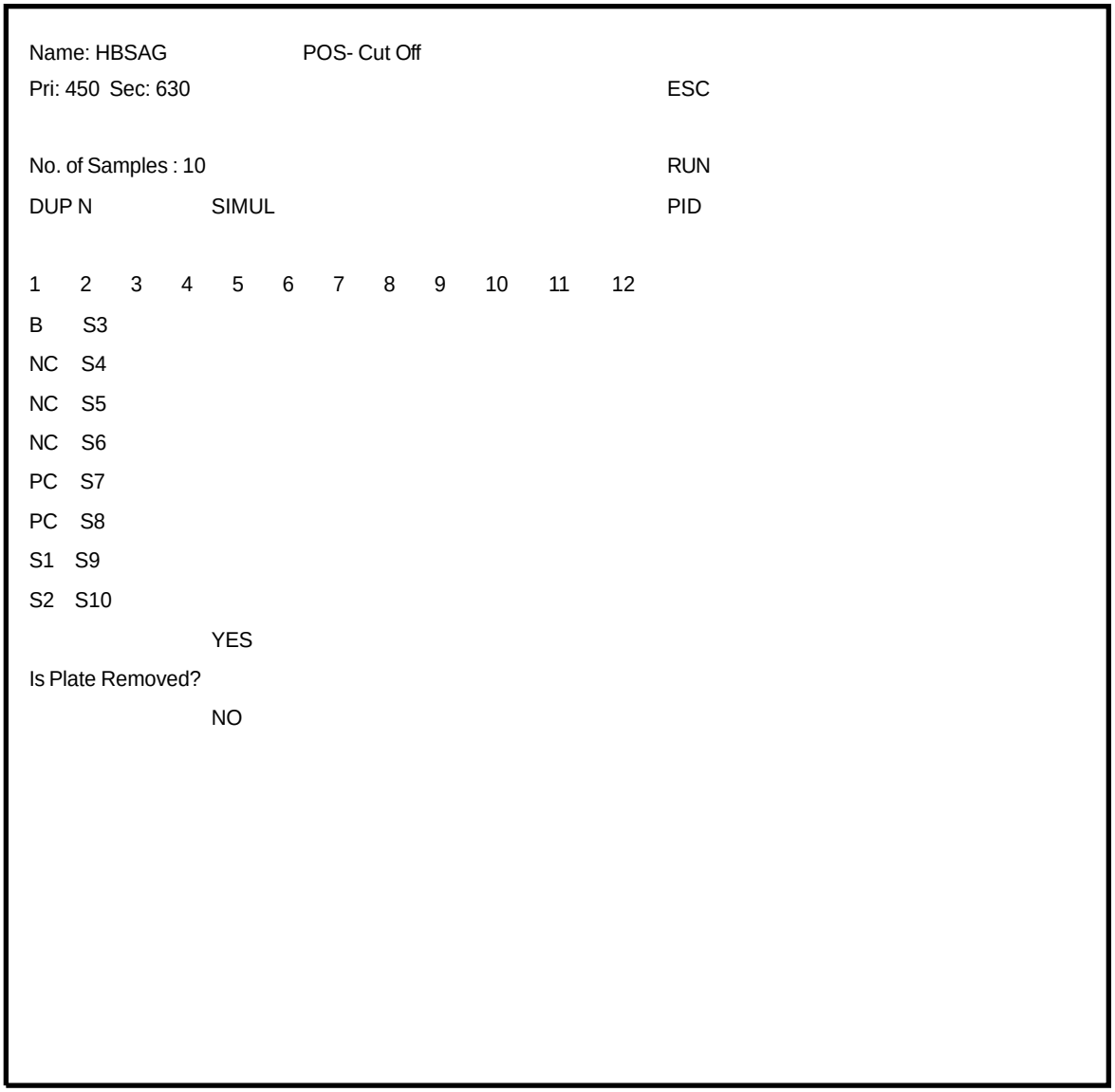
YES
Is Plate Loaded

User Manual

D) Here the plate is loaded in the direction that controls should go in first. Press "YES".

The instrument will read the controls and samples.

The following message appears: "Is plate removed? YES / NO". You remove the tray and press YES.



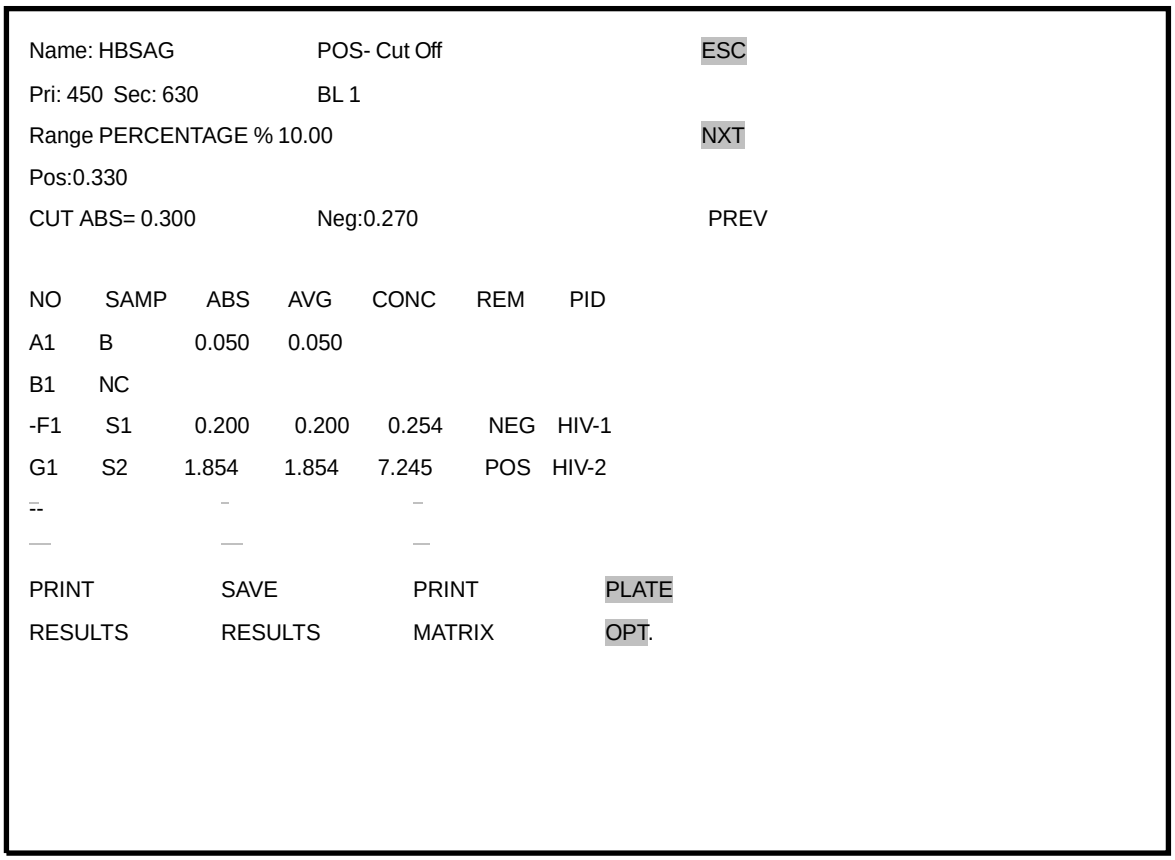
User Manual

E) After pressing YES, result screen will appear with the measured values of average blank, average of all controls and the cut off absorbance.

Name: HBSAG			POS- Cut Off					
Pri: 450 Sec: 630							ESC	
							No	
	Factor	QC	QCVal	Mes.	Rem	ACCEPT		
BL 1		Y	0.100	0.050		TEST		NC
	3	1.000	Y	0.150	0.098			
PC 2	0.100	Y	0.500	2.658		PRINT		
LC 0	1.000	N						
CC 0	1.000	N						
CUTFAC: 0.200			CUTABS: 0.563				Display	
						VALUE:		
QC1 2.560		QC2						
QC3	QC4					LOAD		
						NEXT		
Range % 10.00								

User Manual

F) To check the results of samples, select option 'Display value:



G) By selecting 'ACCEPT TEST' option you can save this test with the details of controls absorbance. Next time it is possible to run the same test without loading controls. This means that the previous stored values of controls can be used

All the details are in table format, as per row and column shown on the screen. You obtain the print of the same format by selecting option 'PRINT RESULTS'. To check the results of next samples, choose option 'NXT', and than print it in format as shown on the screen by option 'Print Results'

You can obtain the print in matrix format, by selecting option 'PRINT MATRIX'.

In matrix form you will get the print as per your tray/plate for all the wells. Instrument prints seven different parameters in print matrix for a single well.

ROW IDENTIFICATION	A,B, C,D,……
WELL NUMBER	W1, W2, W3, W4…..
WELL ID OR SAMPLE NUMBER	BL, NC, PC, OR S1, S2, S3, …..
PATIENT IDENTIFICATION	RAMESH, VIKAS, etc.
WELL ABSORBANCE	0.050, 0.098, 0.085, …
SAMPLE CONCENTRATION	0.738, 0.689, 2.578,…
INTERPRETATION / REMARKS	POS or NEG or EQ

9.2. A. Invalid Assay in Cut Off Mode

If any individual control behaves incorrectly and it's absorbance is not satisfying the QC checkvalue of that control , the following message appears: "Invalid Assay" and a remark "HI" or "LO" for that control. OR if the QC1, QC2, QC3 and QC4, which has an other QC condition of controls (like some reagent manual gives condition PC-NC > 0.2 or NC/PC > 0.5)the following message appears: "Invalid Assay" and a remark either 'HI' or 'LO' for that QC condition.

Name: HBSAG POS- Cut Off

Pri: 450 Sec: 630 ESC

No

	Factor	QC	QCVal	Meas.	Rem	ACCEPT
BL 1		Y	0.100	0.105	HI	TEST
NC 3	1.000	Y	0.150	0.200	HI	
PC 2	0.100	Y	0.500	0.456	LO	PRINT
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.200 CUTABS: 0.563 Display

VALUE:

QC1 2.560 HI QC2

QC3 QC4 LOAD **Invalid**

Assay NEXT

(NOTE: The absorbance of controls should not go above 3.50. If it is > than 3.50, it will show the remark 'HI' for that control. In such a case edit the control absorbance.)

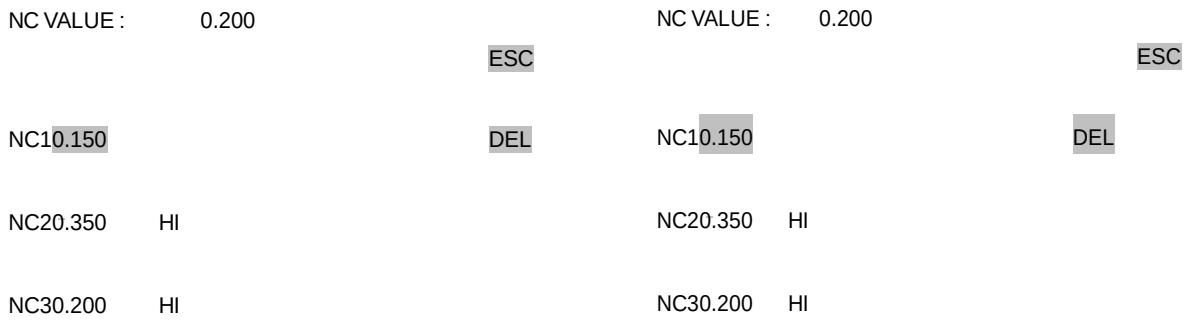
User Manual

In such case, delete an individual control, so that the average of remaining controls will satisfy the QC condition of that control as per reagent manual.

To select any control for deleting, you select touch zone shown in the above screen.

When you select any particular control for deleting (suppose you have selected Negative Control (NC), 'HI' or 'LO' remark appear on the screen.

"Select EDIT / DEL key to proceed". To delete the control select 'DEL'.After deleting that control, the absorbance of that control will become zero and the average of controls will also get changed. Select 'ESC' key to go back.



When you go back, you will get the edited value for average of control with no remark for any control and no "Invalid Assay" message.

***NOTE**:

Make the blank absorbance valid in case the absorbance doesn't meet the QC conditions.

If necessary valid the control absorbances because the absorbance of the blank affect the absorbance of all controls and samples.

It is recommended that, for a test with single blank and single control, if absorbance doesn't satisfy QC conditions or if all controls of any single type (means all NC controls or all PC controls) doesn't meet the QC, the test will become totaly invalid. It is not possible to make the VALID TEST and new controls have to be loaded.

User Manual

Multi Standard Mo

Name: TSH MULTISTANDARD
Pri: 450 Sec: 630 BL Y 0.000 CAL 7 ESC
DUP N DUP N
EDIT
Graph : LINEAR
Y vs X : ABS vs CONC RUN

HI CO : N High>25.03 PRINT
Low<10.54

LO CO: N High>16.61
Low<5.45
Interpretation: Y
Range High> 15.25
Low< 9.46
To change values press EDIT

A)Run this test by selecting RUN option. Following screen will appear.

Name: TSH MULTISTANDARD
Pri: 450 Sec: 630 ESC

No. of samples : 0 RUN
DUP N SIMUL PID
1 2 3 4 5 6 7 8 9 10 11 12
B
C1
C2
C3
C4
C5
C6
C7

HI CO: 0
COL
ROW

B) To enter total N° of HI controls you want to load in the plate select "HI CO :" option and enter numeric value.

Numeric Value

1 2 3 4 5 6 ENTER

7 8 9 0 . CLEAR

C) If you select N° of HI controls TWO.

Then you have to locate the position of HI controls by selecting column number and row number.

For column number entry select "COL" key and enter column number.

HI CO : 2

ROW COL

2

3

Please Enter Col Entry: 1

Numeric Value:

1 2 3 4 5 6 ENTER

7 8 9 0 . CLEAR

For row entry select "ROW" key and enter row position.

HI CO : 2

ROW COL

A 2

B 3

Please Enter Row Entry: 1

User Manual

D) You have to locate controls from first well or after last calibrator to last well of strip 12 in any test.

Suppose you select column 2 & row A for first HI control and column 3, row B for second HI control than the location of HI control will be display on screen. As shown in screen below.

Name: TSH MULTISTANDARD
Pri: 450 Sec: 630 ESC

No. of samples : 0 RUN
DUP N SIMUL PID
1 2 3 4 5 6 7 8 9 10 11 12
B HC
C1 HC
C2
C3
C4
C5
C6
C7

HI CO: 2
COL
ROW

E) Select N° of samples you want to run. In case of 12 samples, the following screen will appear.

Name: TSH MULTISTANDARD
Pri: 450 Sec: 630 ESC

No. of samples : 12 RUN
DUP N SIMUL PID
1 2 3 4 5 6 7 8 9 10 11 12
B HC S8
C1 S1 HC
C2 S2 S9
C3 S3 S10
C4 S4 S11
C5 S5 S12
C6 S6
C7 S7

F) Press run to start reading operation.

The tray will come out. The following message appears: “Is Plate loaded YES / NO”.

The tray has to be loaded in a direction that calibrators should go in first and press YES.

The instrument will read the absorbance of calibrators and samples.

“Is plate removed? YES / NO”. Remove the tray and press YES.

The Tray holder will go inside and on the screen all details of calibrators, samples and controls are shown.

```
Name: TSH                  MULTI STANDARD                    ESC
Pri: 450  Sec: 630         BL Y      CAL 7
Range   High > 16.61        Low < 10.30                       NXT
HI  CO :  High >           Low < 0.000
LO CO : High >             Low <
                                                             PREV
NO     SAMP    ABS    AVG    CONC    REM     PID
A1     B       0.050  0.050                                  SAVE
B1     C1      0.070  0.070  0.000                           RESULT
C1     C2      0.257  0.257  2.500
--
--
--
F1     S1      0.200  0.200  2.100    NEG    TSH-1
G1     S2      1.854  1.854  9.845    POS    TSH-2

LOAD   PRINT   PLATE  VIEW   ACCEPT   PRINT
NXTMATRIX      OPT.   GRAPH: TEST     RESULTS
```

All the details as per row and column are shown on the screen. The printout of the same format can be obtained by selecting option ‘PRINT RESULTS’. To check the results of next samples, choose option ‘NXT’and print the format shown on screen by option ‘Print Results’.

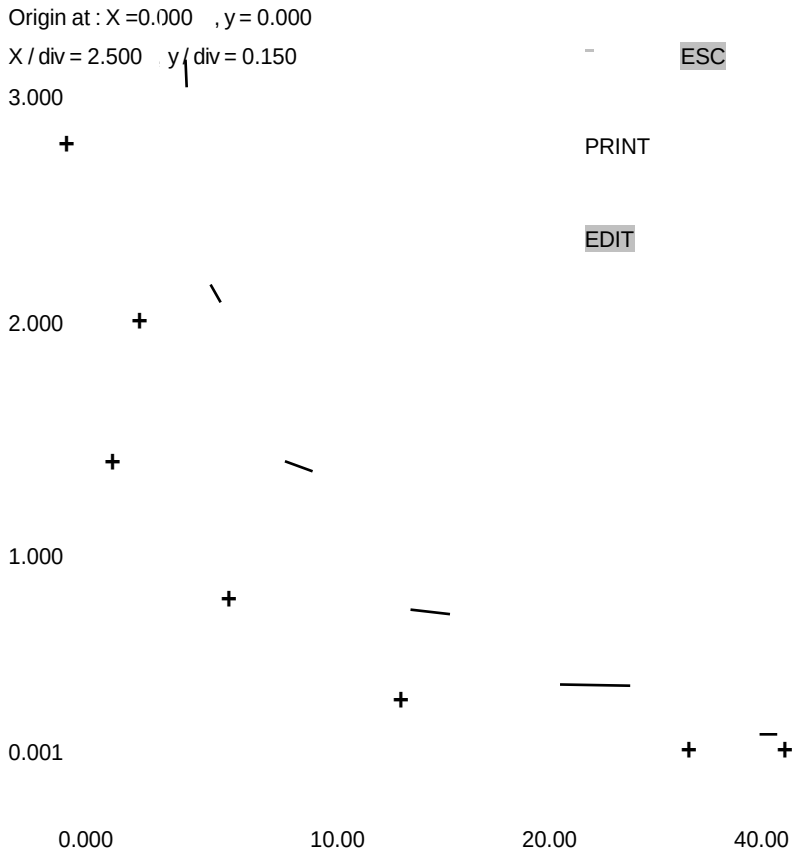
You can get the print in matrix format, by selecting option ‘PRINT MATRIX’.

In matrix form you will get the print as per your tray/plate for all the wells. Instrument will print seven different parameters in print matrix for a single well as follows:

User Manual

ROW IDENTIFICATION	A,B, C,D,……
WELL NUMBER	W1, W2, W3, W4…
WELL ID OR SAMPLE NUMBER	B, C1, C2, C3, OR S1, S2, S3,..
PATIENT IDENTIFICATION	RAMESH, VIKAS, etc.
WELL ABSORBANCE	0.050, 0.098, 0.085, …
SAMPLE CONCENTRATION	0.738, 0.689, 2.578…
INTERPRETATION / REMARKS	POS, NEG, EQ,

G) **By selecting option 'View Graph:' key, the graph appears on the screen, with all the details of X-axis and Y-axis. Select 'PRINT' option to obtain the print out.**



Select ‘ACCEPT TEST’ option to save this test with the details of calibrator absorbance. It is possible to run the same test without loading calibrators. The previous graph can be used for new samples.

(* NOTE: If you do not want to run the calibrators each time, please select “ACCEPT TEST” option to save graph, whenever you run the test with calibrators.)

User Manual

9.3.A. Invalid assay in Multi standard Mode

In Multi standard, the absorbance of calibrators should be in increasing or decreasing from one calibrator to the next calibrator. If any calibrator/s behave(s) incorrectly you will obtain a message "Invalid Assay" at bottom side of screen.

Name: TSH MULTI STANDARD ESC
Pri: 450 Sec: 630 BL Y CAL 7
Range High > 16.61 Low < 10.30 NXT
HI CO : High > Low < 0.000
LO CO : High > Low <
PREV

NO	SAMP	ABS	AVG	CONC	REM	PID	
A1	B	0.050	0.050				SAVE
B1	C1	0.070	0.070	0.000			RESULT
C1	C2	0.257	0.257	2.500			

--------**Invalid Assay**

LOAD	PRINT	PLATE	VIEW	ACCEPT	PRINT
NXT	MATRIX	OPT.	GRAPH:	TEST	RESULTS

In such a case "EDIT" option is available on the GRAPH screen. If you select EDIT, the following screen will appear:

CAL 1	2.562	ESC	CAL 1	2.562	ESC
CAL 2	1.865		CAL 2	1.865	
CAL 3	2.050		CAL 3	2.050	
CAL 4	1.054		CAL 4	1.054	
CAL 5	0.648		CAL 5	0.648	
CAL 6	0.356		CAL 6	0.356	
CAL 7	0.045		CAL 7	0.045	

Numeric Value:
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR

You can easily select any particular calibrator by touching that touch zone and edit the absorbance of that. After editing the calibrator's absorbance select "ESC". A message will appear: "PLEASE WAIT…" and the modified graph will appear on the screen.

(*NOTE: SAME PROCEDURE CAN BE USED TO CREATE AND RUN THE TEST IN ALL OTHER MODES, LIKE SINGLE STANDARD, % ABSORBANCE AND UPTAKE.)

User Manual

10. RERUNNING ACCEPTED TESTS / PROGRAMS

"ACCEPT TEST" option is used to store the data of controls or calibrators (refer to chapter 9.2, 9.3). After running any test first time with controls or calibrators, you select option "Accept Test" to save the data of controls or calibrators, so that next time when you want to load the same test, there is no need to load controls or calibrators in ELISA plate. You can use previously stored data.

A) In "CUT OFF" Mode:

Name: HBSAG POS- Cut Off

Pri: 450 Sec: 630 ESC

No

		Factor	QC	QCVal	Mes.	Rem	ACCEPT	
BL	1		Y	0.100	0.050		TEST	NC
		3	1.000	Y	0.150	0.098		
PC	2	0.100	Y	0.500	2.658		PRINT	
LC	0	1.000	N					
CC	0	1.000	N					

CUTFAC: 0.200 CUTABS: 0.563 Display

VALUE:

QC1 2.560 QC2

QC3 QC4 LOAD

NEXT

Range % 10.00

B) In "Multi standard" Mode:

Name: TSH MULTI STANDARD ESC

Pri: 450 Sec: 630 BL Y CAL 7

Range High > 16.61 Low < 10.30 NXT

HI CO : High > Low < 0.000

LO CO : High > Low <

PREV

NO	SAMP	ABS	AVG	CONC	REM	PID
A1	B	0.050	0.050			
B1	C1	0.070	0.070	0.000		
C1	C2	0.257	0.257	2.500		
F1	S1	0.200	0.200	2.100	NEG	TSH-1
G1	S2	1.854	1.854	9.845	POS	TSH-2

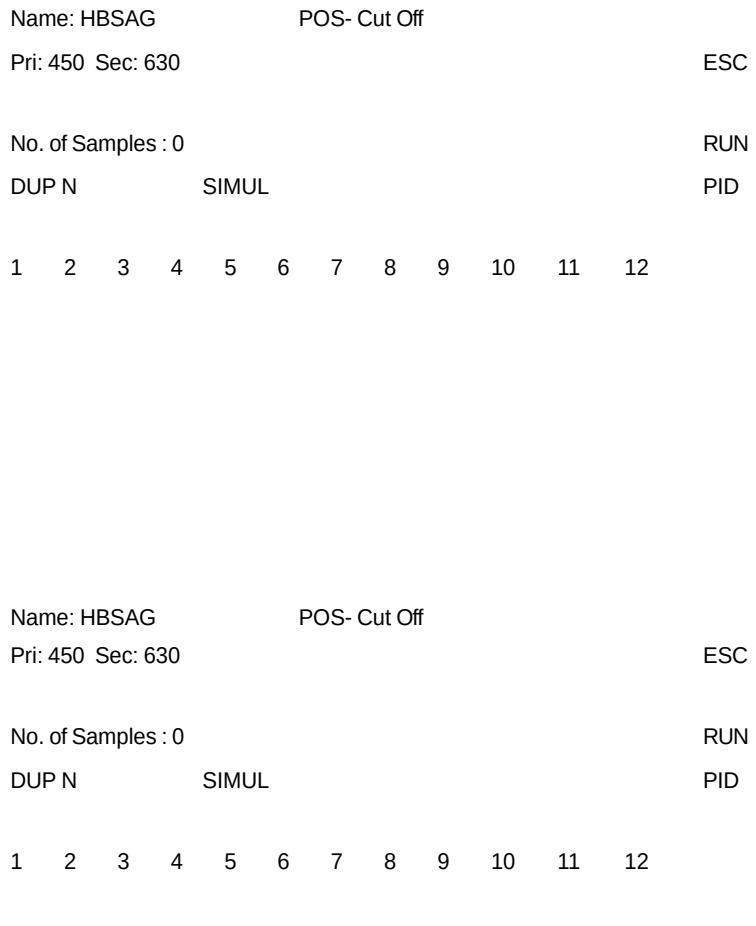
SAVE

RESULT

LOAD	PRINT	PLATE	VIEW	ACCEPT	PRINT
NXTMATRIX		OPT.	GRAPH	TEST	RESULTS

User Manual

When you want to run such an accepted test, select 'RUN' option in test detail screen, in "CUT OFF" mode:



This time, the blank and controls will not be loaded directly and you will get the following question: "Load Blank? YES / NO" and "Load Controls? YES / NO".

If you are running both, select 'YES', and if you want to use earlier stored data / graph of controls select 'NO', so that you can run only samples to get their results without loading control and calibrators.

If you want to load only 'Blank',select "Load Blank? YES" and "Load Controls? NO".

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C) In Multi Standard / Single Standard / % Absorbance / Uptake Mode:

Name: HBSAG POS- Cut Off
Pri: 450 Sec: 630 ESC

No. of Samples : 0 RUN
DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12

In Calibrator Mode, after asking "Load Blank? Yes / No" you will get the following question "Load Calibrators? Yes / No". If you are loading new calibrators and want the results of samples as per new graph select "Load Calibrators? YES".

If you are not loading new calibrators and want to use previously stored graph select "Load Calibrators? No".

If you want to load only 'Blank', select "Load Blank? YES" and "Load Calibrators? NO".

11.SAMPLE AND SAMPLE DUPLICATE

While loading the samples you can load a single sample in single well or a single sample in adjacent two well and finally the instrument will take the average of it as known as Sample Duplicate.

The instrument will load the controls / calibrators automatically in any new test or not accepted test. You have to provide the number of samples. If you are loading single samples keep "DUP"-No. Select "No. of Samples:" to enter total samples.

Name: HBSAG POS- Cut Off
Pri: 450 Sec: 630 ESC

No. of Samples : 0
RUN
DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12
B
NC
NC
NC
PC
PC

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Name: HBSAG POS- Cut Off

Pri: 450 Sec: 630 ESC

No. of Samples : 0

RUN

DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12

B

NC

NC

NC

PC

PC

Numeric Value:

1 2 3 4 5 6 ENTER

7 8 9 0 . CLEAR

Name: HBSAG POS- Cut Off

Pri: 450 Sec: 630 ESC

No. of Smples : 10 RUN

DUP N SIMUL PID

1 2 3 4 5 6 7 8 9 10 11 12

B S3

NC S4

NC S5

NC S6

PC S7

PC S8

S1 S9

S2 S10

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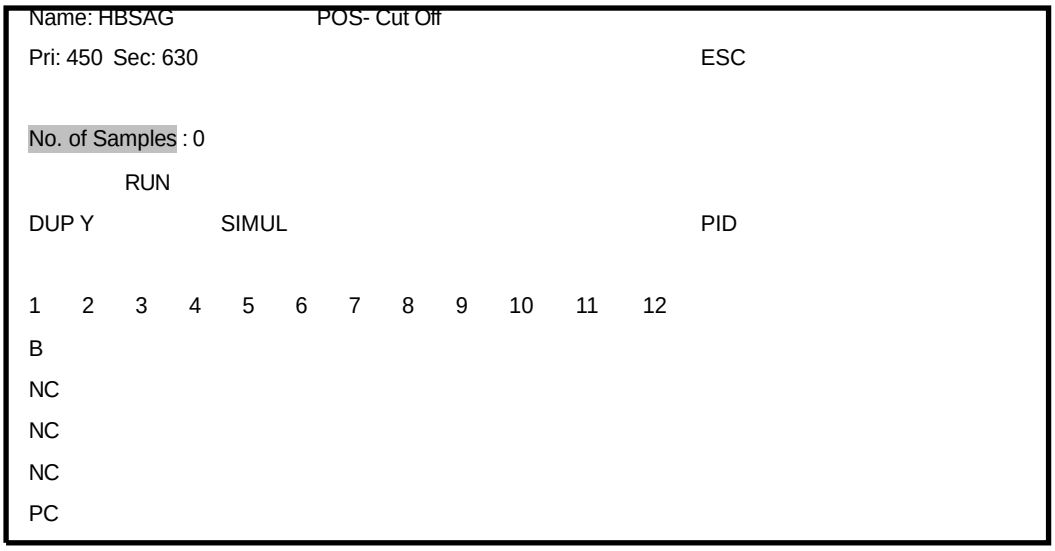
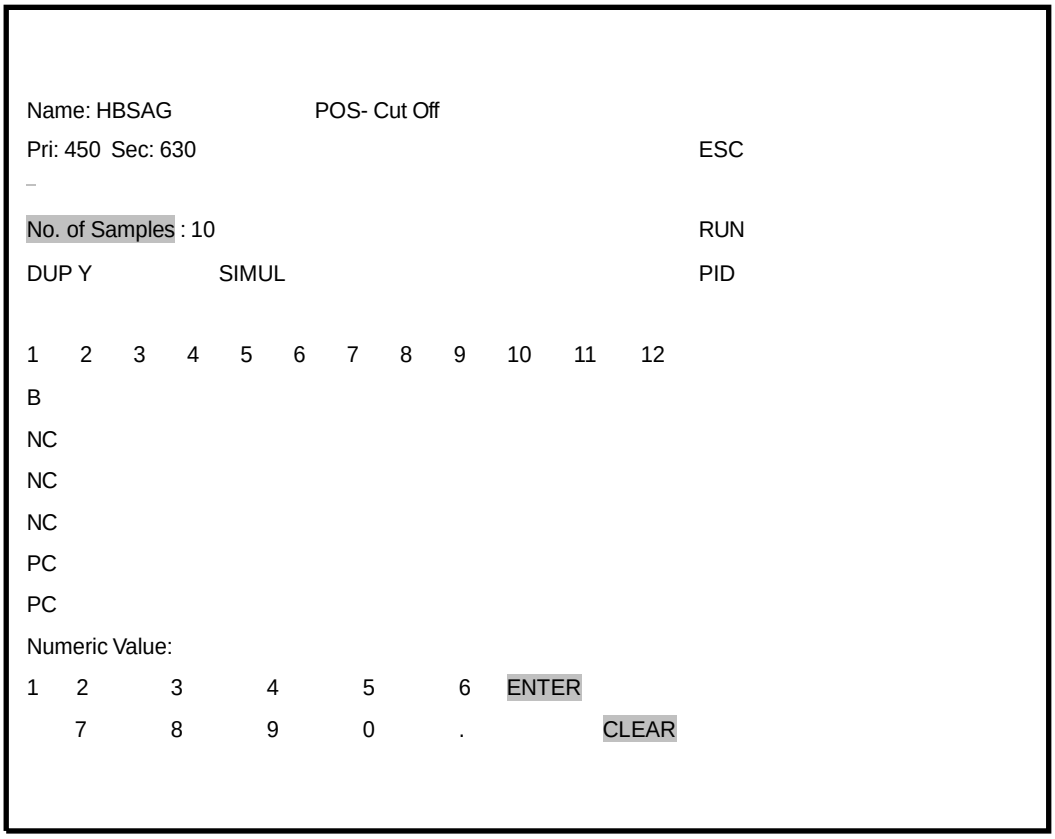
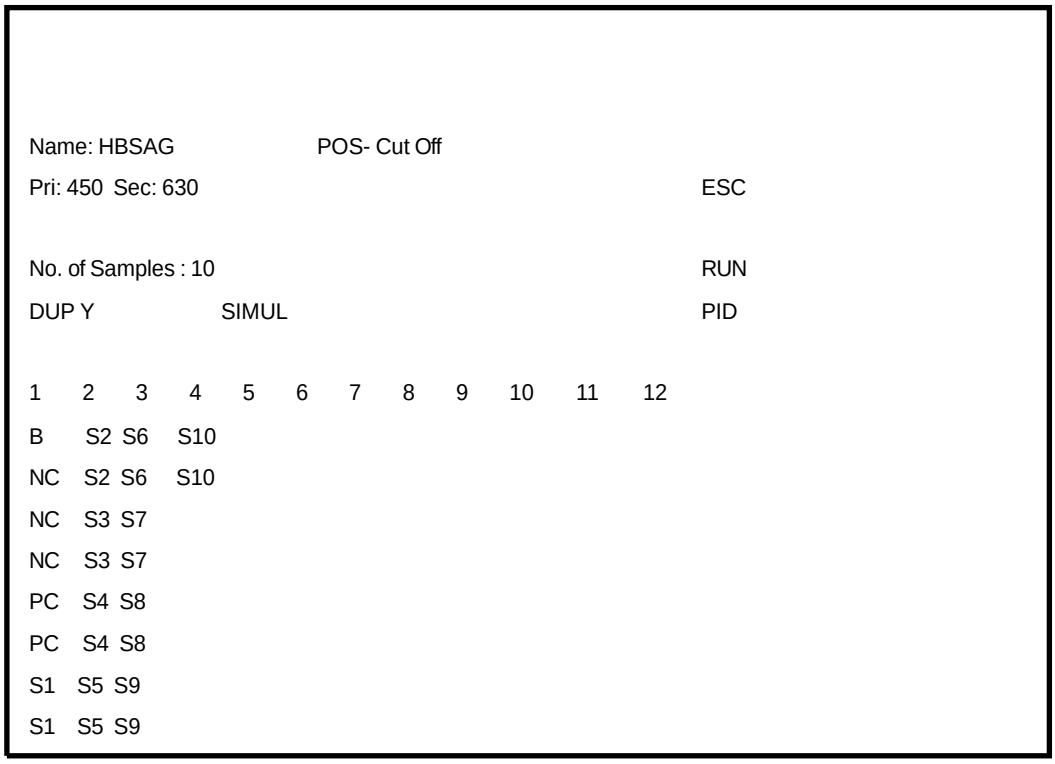
If you want to load duplicate samples select “DUP” key, and on the screen ‘N’ change to ‘Y’.
After this, enter number of samples by selecting “No. of Samples”.





User Manual



(* Same way you load the samples and Sample Duplicates in all other modes)

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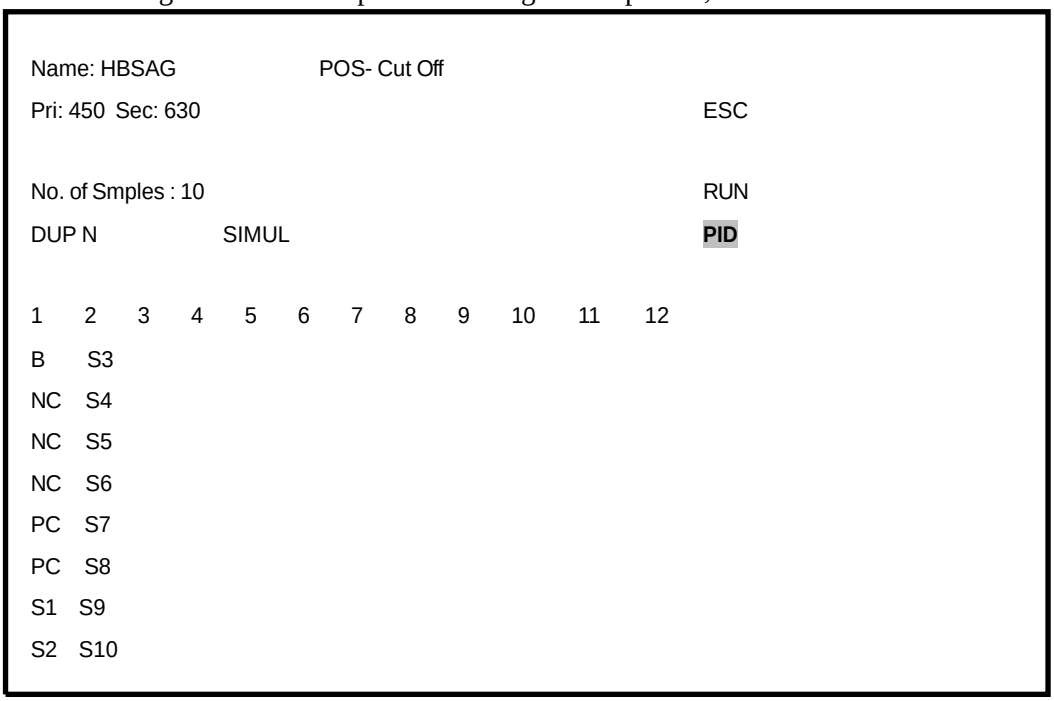
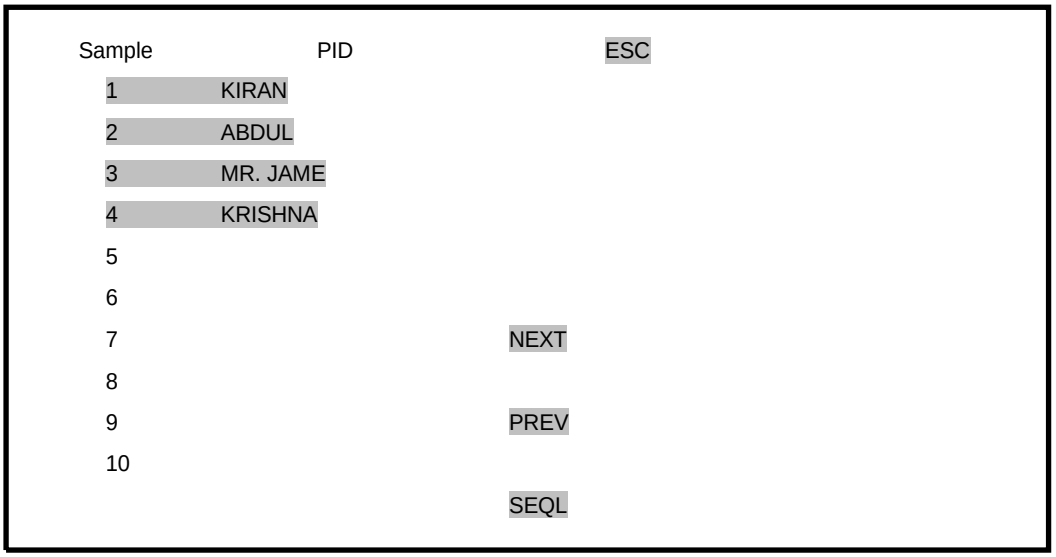
12.PATIENT IDENTITY / SAMPLE IDENTITY ENTRY

A.) To enter a patient ID for all samples there is option provided in loading screen shown as "PID".

After entering number of samples either single or duplicate, select "PID".





One by one you can enter name of each patient. The character length of PID is only 7 characters.

Go to the next and previous screen with "NEXT" and "PREV"

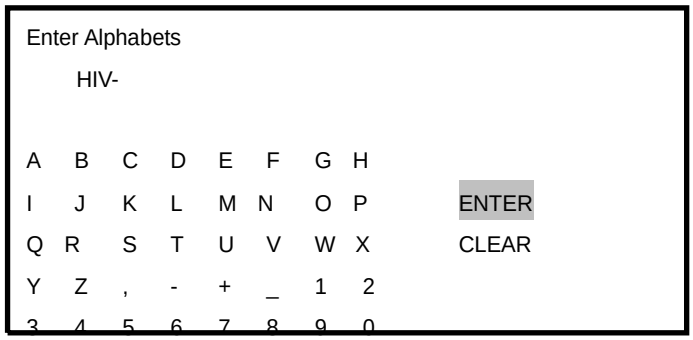
B).Sequential Patient ID Entry

This one by one entry will take more time, therefore one more option to enter patient Ids is provided . This option is “SEQL”sequential entry.

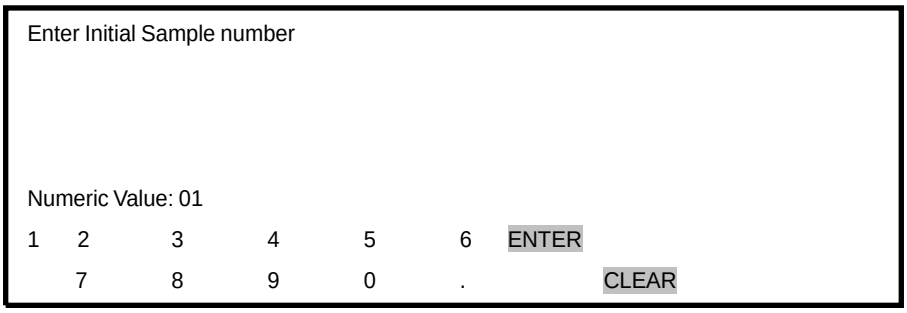
If you select “PID” option for patient ID entry, the following question appears on the screen:, “Delete Previous PIDs, Yes / No”. If you select NO, it will directly load the previously entered PIDs for sample and if you say YES, it will delete the previous PIDs.

After selecting ‘NO’, select “SEQL” option to enter different sequential PIDs. And follow the steps as follows:

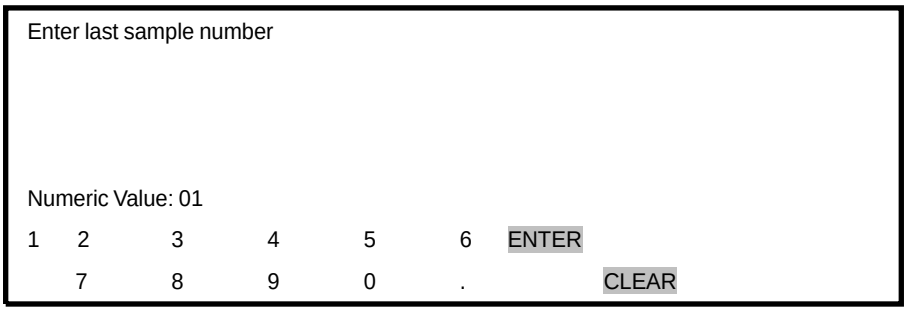
C) Enter Initial Alphabets. Maximum 4 characters



D) Enter Initial well Number. This is the starting well location of that particular batch.

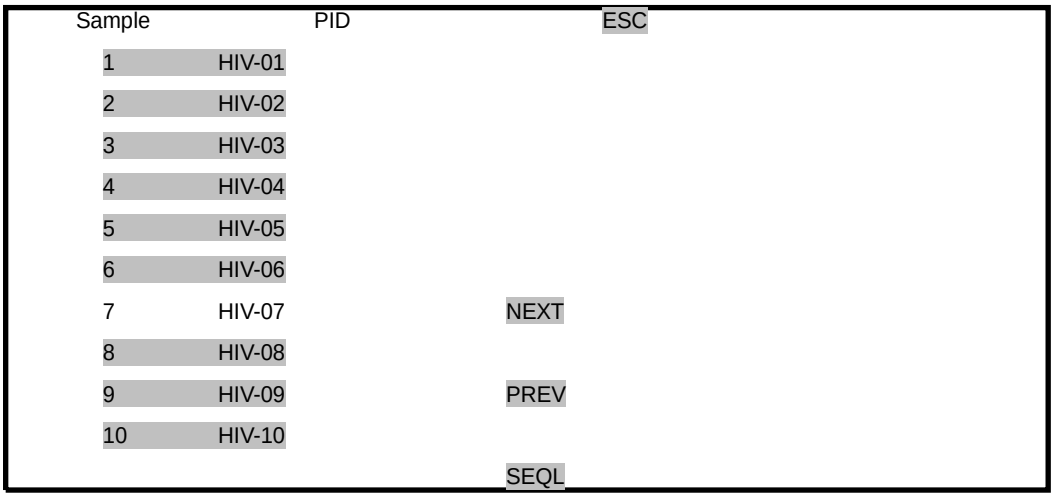


E) Enter last well Number. This is last well location of that particular batch.



F) Enter initial PID Number. This is the starting number of that particular batch, maximum 3 digits.

The final screen will appear which displays the sequential IDs of patient samplesfor the well location that is selected.



In case there are totally 70 N° of samples from three different batches which are loaded in a single plate, than the PID For the first batch are from HIV 1 to HIV 30, for second batch PIDs are from HIV 51 to HIV 75 and the third batch has PIDs from HIV 91 to HIV 105.

To enter these PIDs, you have to enter sequential entries three times, use following steps:

Select 'SEQL', Enter alphabet 'HIV'. Enter initial well number '1' and the last well number '30', after this enter initial PID number '1'. It will load PIDs for first 30 samples from HIV 1 to HIV 30.

To enter next sequence again select ‘SEQL’, enter alphabet ‘HIV’. Enter initial well number ‘31’ and last well number ‘55’. After this enter initial PID number ‘51’. It will load PIDs for next 25 samples from HIV 51 to HIV 75.

To enter next sequence again select ‘SEQL’, enter alphabet ‘HIV’. Enter initial well number ‘56’ and last well number ‘70’. After this enter initial PID number ‘91’. It will load PIDs for next 15 samples from HIV 91 to HIV 105.

In this way you can select any sequence for any well locations.

(*NOTE: The entered PID get stored in instrument memory, until you delete it by using option, “Delete previous PIDs? Yes / NO.”)

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13.SAVE PLATE AND SAVE RESULTS

In all modes of operation, there are two options provided to store results.

A) In cut Off mode:

Name: HBSAG	POS- Cut Off	ESC
Pri: 450 Sec: 630	BL 1	
Range PERCENTAGE % 10.00		NXT

NO	SAMP	ABS	AVG	CONC	REM	PID	PREV
A1	B	0.050	0.050				
B1	NC						

B) In Multi standard or any calibrator mode:

Name: TSH	MULTI STANDARD			ESC
Pri: 450 Sec: 630		BL Y	CAL 7	
Range High > 16.61	Low < 10.30			NXT
HI CO : High >	Low < 0.000			
LO CO : High >	Low <			
				PREV

NO	SAMP	ABS	AVG	CONC	REM	PID	
A1	B	0.050	0.050				SAVE
B1	C1	0.070	0.070	0.000			RESULT
C1	C2	0.257	0.257	2.500			

If “PLATE OPT.”is selected , you will obtain two options.

“SAVE PLATE DATA”,

which will save the entire plate information along with the control/calibrator information.

(maximum TEN plates data can be saved).

“SEND PLATE DATA” is used to send the data from instrument to computer through USB or serial RS232 connection.

1. SAVE PLATE DATA

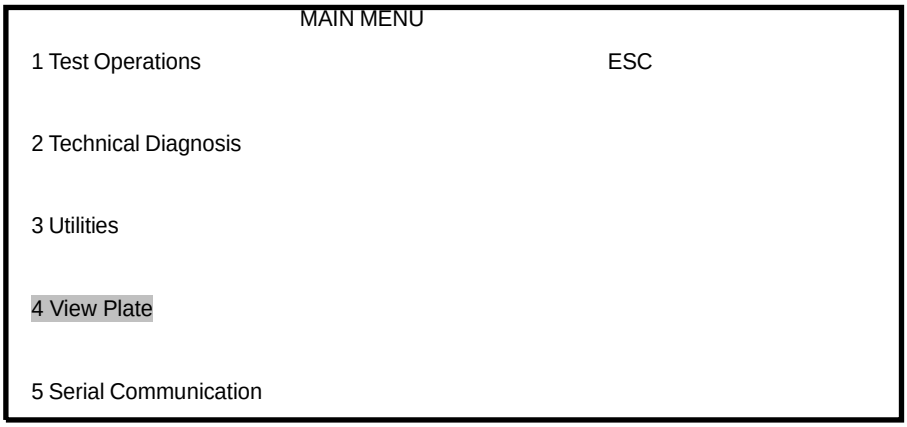
ESC

2. SEND PLATE DATA

If “SAVE RESULT” option is selected the information of samples only except controls/calibrators, with test name, patient ID and date will be saved.

14.VIEW STORED DATA

The stored plate or stored results appear on the screen by selecting option “View Plate” in “MAIN MENU”.



Two options appears on the screen by selecting “View Plate” option

1. PLATE RESULTS

ESC

2. PATIENT RESULTS

1)The details of stored plate (last 10 plates) with date, test name and mode of operation in descending order from last to first will appear on the screen by selecting . “PLATE RESULTS”
Any test can be selected. The complete information will appear on the screen.
“Print Matrix” will print the details of entire plate in matrix format as explain earlier.
“Print” will print only the data displayed on screen.
“Send data” can be used to send the data from instrument to computer through USB or serial RS232 connection.

2.) “PATIENT RESULTS” will show the details of all samples, saved in memory using option “SAVE RESULTS” in all different modes, as explain earlier. This option will display the data in table format as shown below. Test name, Mode of test operation, result of sample, PID and Remark will appear on the screen. The instrument has a memory to store 2500 sample results.
This option doesn’t show the information of controls or calibrators.

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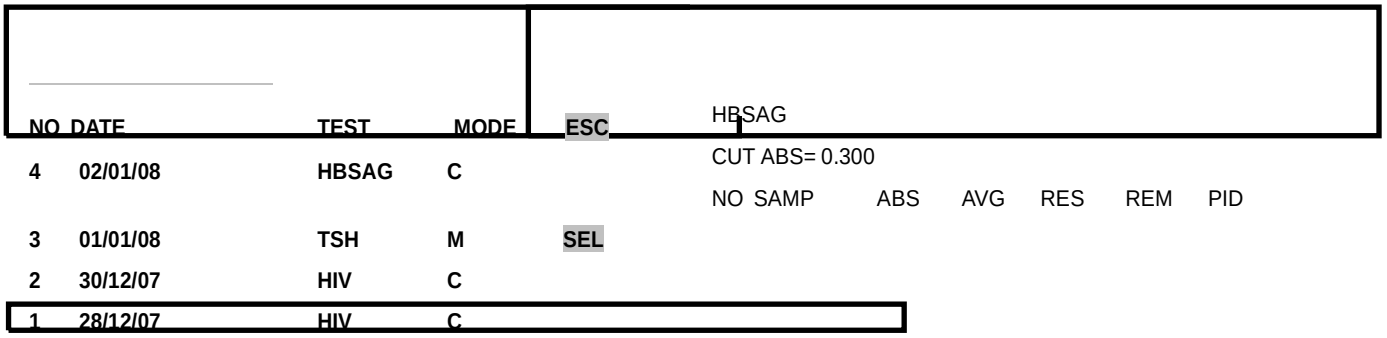

"PRINT" is used to print the details as available on the screen.
"NEXT" and "PREV" option are used to go to next page of sample details and to go back to previous page.

(*NOTE: When there is not enough memory the following message appears:
"Memory Left for samples- First Samples Deleted")
The instrument automatically deletes a number of samples that are stored in the beginning and than save the new samples at that location.

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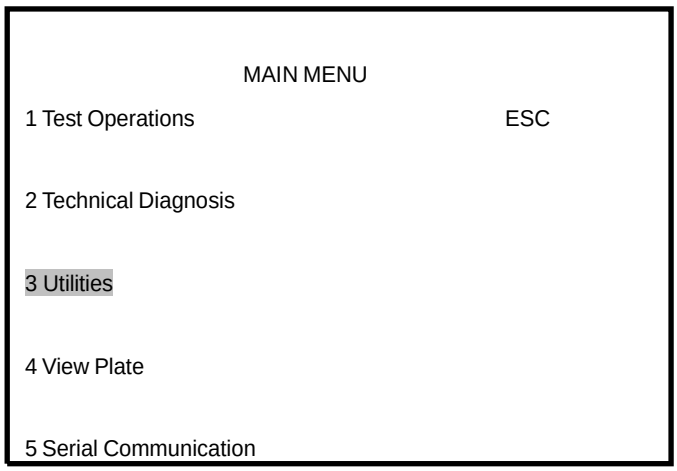
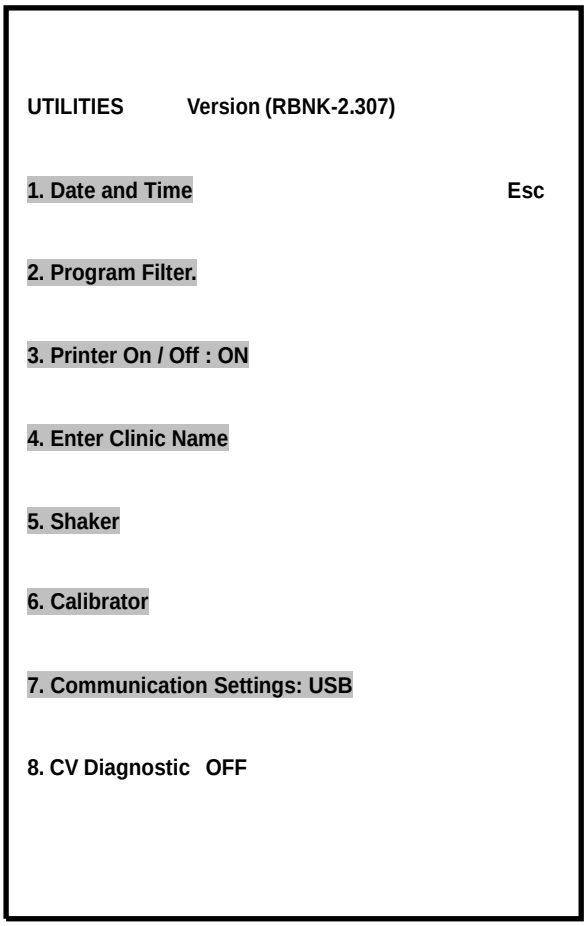
15. UTILITIES

In utilities there are seven different functions





15.1. Date and Time Setting

Set current Date and Time by

Selecting DD, MM, YY and

Hrs, Min, Sec.

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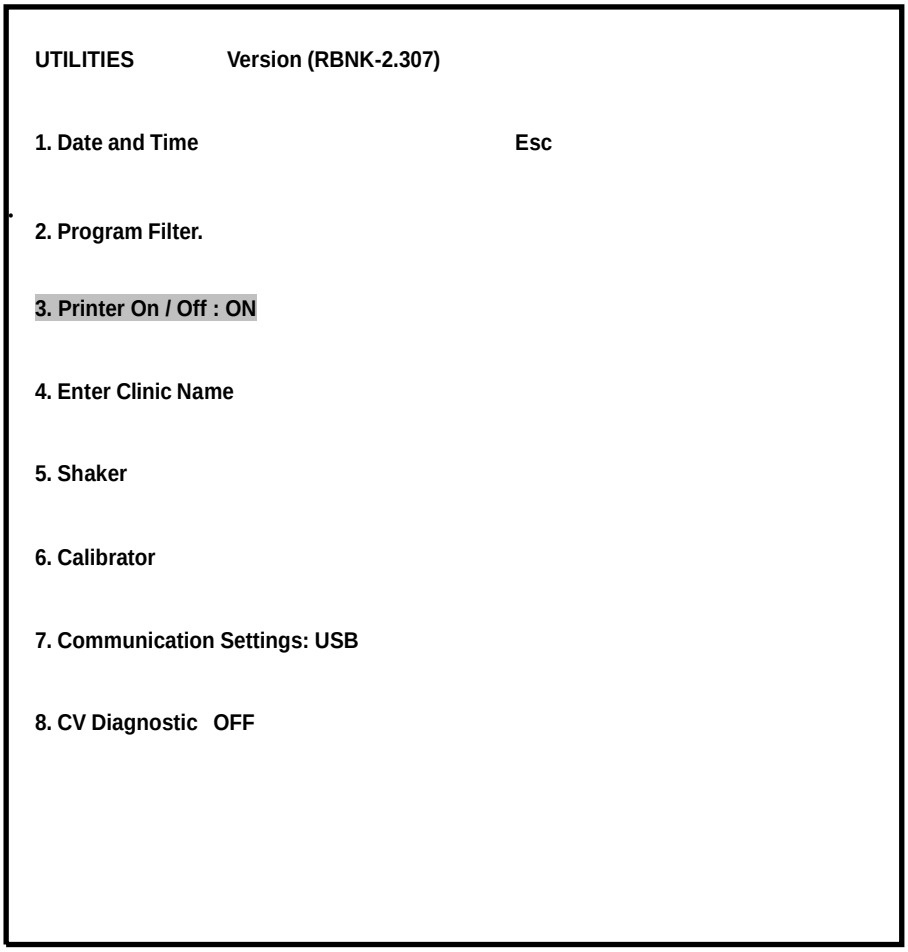
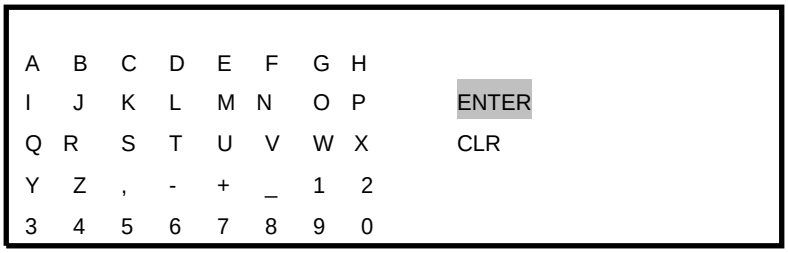
15.2. Printer On / Off setting

to turn PRINTER On and OFF .

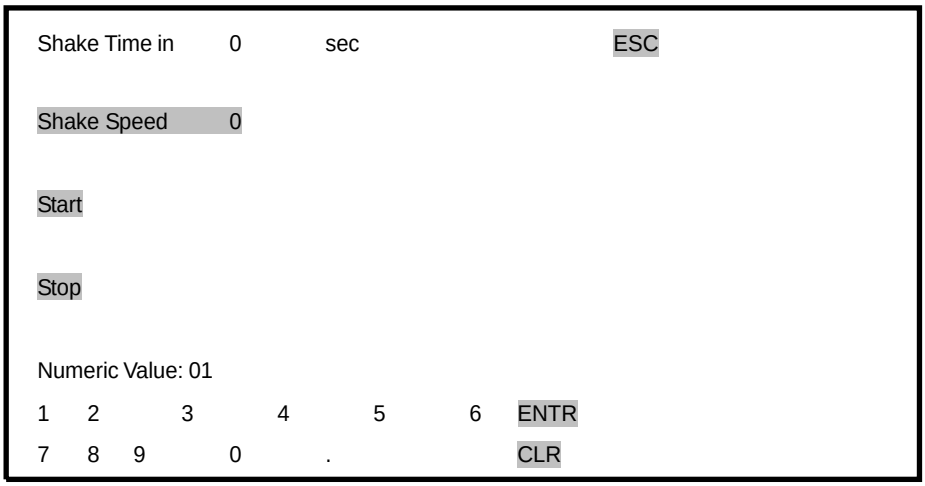


15.3.Clinic Name Entry

Type your Clinic Name and select “ENTER”. The character length is maximum 19 characters



15.4. Plate Shaking Mode (Shaker)



The total shake time can be entered in seconds.

Regarding the “Shake Speed”, there are 10 types of speeds. You can choose any speed by entering number from 1 to 10. The shaking speed increases as the number increases.
After entering shake time and shake speed, select Start option. When “Start”is selected, the tray will come out and on the screen you will obtain a message “Is plate loaded? Yes / No”.
After selecting YES the tray will go inside and instrument will do the shaking of plate for the given time period with selected speed.
When the shaking is finished, the play will come out of the tray and display a message “Is plate removed? Yes / No”Remove the tray and press Yes to end the process.

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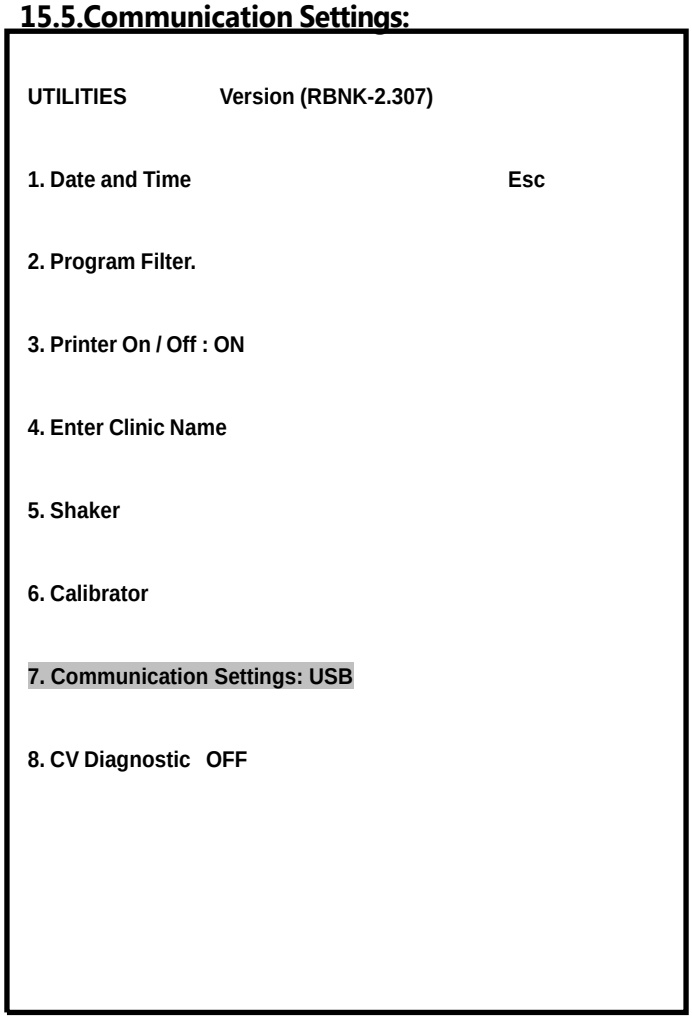
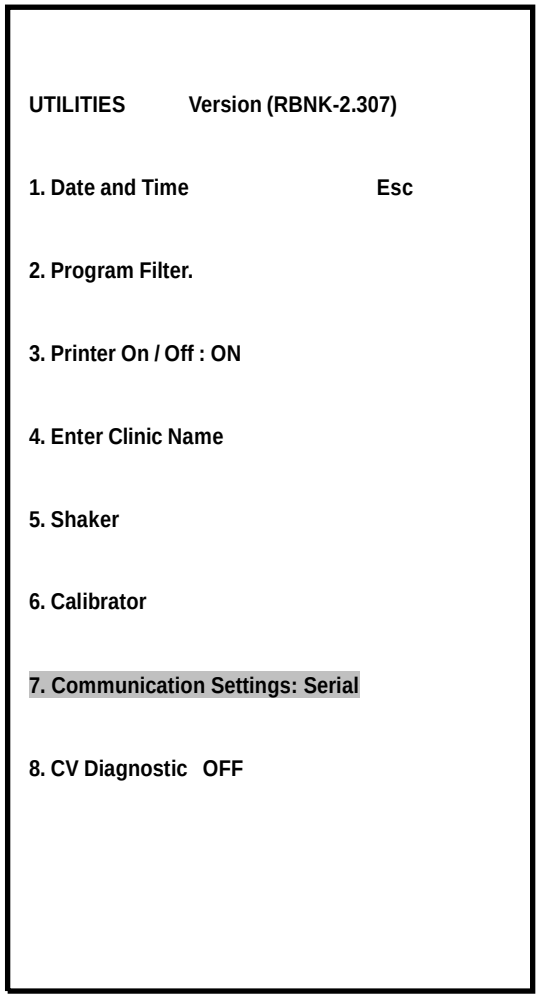
15.5.Communication Settings:





This setting is very important, whenever you want to transfer data from instrument to computer. You can transfer data either using USB or by Serial RS232.

We provide one application which support to this communication between instrument and computer. This application receives data either by USB setting or by Serial setting.

NOTE:The option 6. "Calibrator" is not for users. Do not select this utility and don't change any settings because otherwise the mechanical alignment will get disturbed.
The option 8. "CV Diagnostic OFF" is not for users. It is for factory use only.

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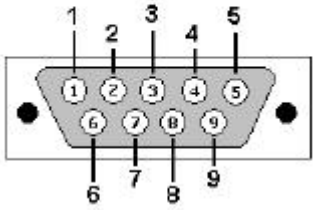
16. SERIAL COMMUNICATION

The instrument is equipped with an RS232 serial port.



1. Test Operations
2. Technical Diagnosis
3. Utilities
4. View Plate
5. Serial communications

SERIAL COMM.

1.Send Results

ESC

SERIAL COMM.

ESC

1.Send Results

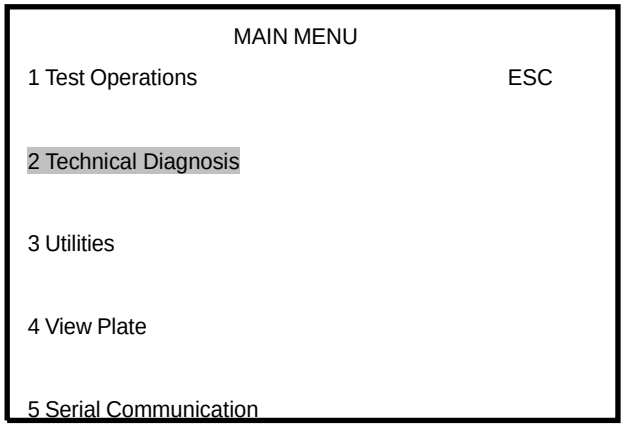
YES

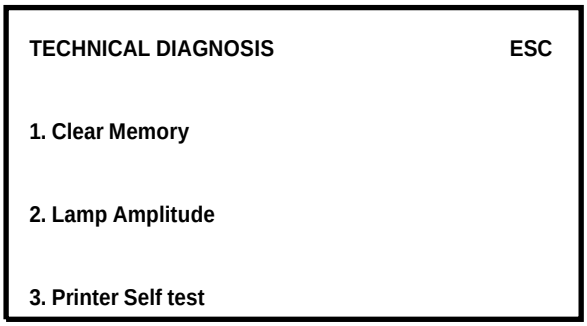
Results

NO

17. TECHNICAL DIAGNOSIS

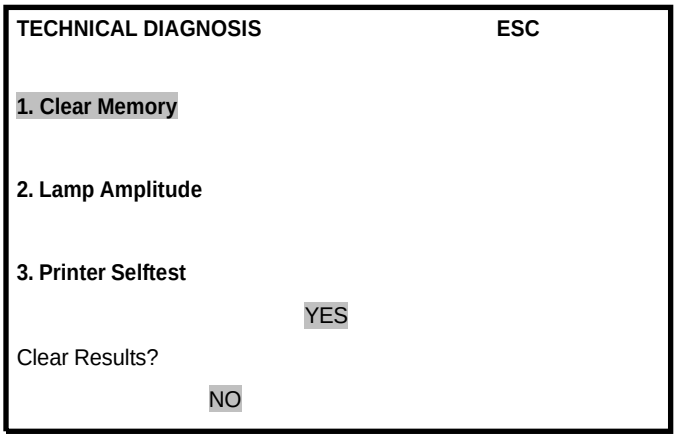
Technical Diagnosis is present in “Main Menu”.





17.1Clear Memory

This option is used to clear entire saved test records and entire saved patient results along with saved plates. The “Test Records” are the different kind of programmed test that are made in different modes of operation and saved in instrument program memory.

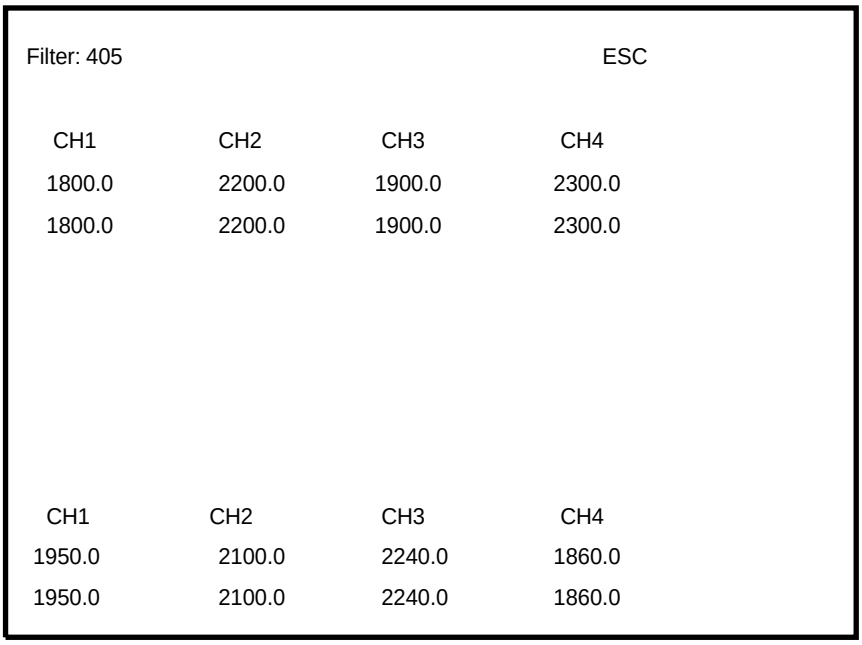


When option “Clear Memory” is selected the instrument will first ask “Clear Results YES / NO”.
If “YES”is selected it will only clear saved patient results and saved plates stored in the memory, and shows message “Clearing Memory …”.
This option does not clear the programmed test saved in instrument memory.
After clearing the memory or if option “NO” is selected the next question appears.

17.2. Lamp Amplitude

This option is used to check the light gain of filters used in the instrument. There are 8- channels used of same type. This option shows the gain of each channel filter in table format. In the instrument the range of amplitude is from 600.00 to 2450.00. If the amplitude goes below 600.00 for any channel, the message "Amp –Low" will appear on the screen for that particular channel if the amplitude goes more than 2490.00, than the over range saturation voltage figure of 2500.00 will be passed.

The gains of filters are set within a required range. When you select this option, the lamps will turn ON, tray holder plate will comes out and the instrument will start showing amplitudes (gains) of all filters one by one.



17.3. Printer Self test

It is used to check the printing of thermal printer. Is it printing perfectly or not?

When you select this, it will print first two lines of Technical Diagnosis Screen.

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18. Trouble Shooting	CAUSE /CORRECTIVE ACTION
1) Printer disabled Disable Printer YES / NO?	You will get this message, if paper is not loaded properly or lever is not at correct position. Check all possibilities. Also check ON LINE and FEED LED glowing or not and when you switch 'ON' the instrument check paper is moving forward or not. If LEDs are not glowing and paper is not moving forward contact service engineer.
2) "Check Light Path!!! CH x" Where 'x' is any channel number X = 1/2/3/4/5/6/7/8	You can get this message in any mode of operation. Before reading absorbance, instrument is checking the filter reference voltages of all 8 channels. If filter voltage of any channel is less than minimum required voltage, it will display a message "Check Light Path!!! CH x". Here 'x' is channel numbers having reference voltage less than minimum required. For ex. If reference voltage of channel 3 is less the message will be displayed "Check Light Path!!! CH 3". It will indicate all channel numbers having less reference voltage, like "Check Light Path!!! CH 1 3 6 " In such a case, there is a possibility of filter gain of that channel isreduced or intensity of lamp of that channel has become poor, so contact factory engineer.
3) Invalid Assay	If in the Cut Off and Multi standard mode the controls and standards are not ok then this error message will appear.
4) Memory Full	If Number of saved tests exceeds the memory limit of 250 tests then delete the unwanted tests and save the test.
5) "Check USB Application on Computer Do you want to continue? YES / NO"	Using data receiving application on computer, 1) If you have not connected the data cable (USB or Serial) correctly, you will get this message. 2) If you have selected 'Communication Setting' (ref. 14.5), USB on instrument, and you have selected a 'Serial' communication on

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	computer data receiving application, you will get this message. In such a case select 'USB' communication, on computer and select 'YES' key to transfer data. To avoid this message, connect proper data cable, select the same communication medium (USB or Serial), on computer data receiving application, which you have selected on instrument 'Communication Setting'.
6) Filter Movement Error!!!	Instrument will display this message, if there is problem with MOC sensor PCB or with filter tray stepper motor. The MOC sensors are used to detect the position of filter tray. These two sensors are mounted on bottom of the mechanism. One detects the home position and second detects the each filter position of filter tray. In such a condition we need to check the connection to these sensor and also the connection of stepper motor, which is used to move filter tray.
7) Plate Movement Error!!!	Instrument will display this message, if there is problem with MOC sensor PCB or with plate carrier stepper motor. The MOC sensors are used to detect the position of plate carrier. These two sensors are mounted on top of the mechanism. One detects the home position and second detects the each strip position of plate carrier. In such a condition we need to check the connection to these sensor and also the connection of stepper motor, which is used to move plate carrier.

User Manual

19. DECONTAMINATION

19.1. Decontamination Procedure

If the instrument has to be shipped after being exposed to potential hazard material, it should be decontaminated. The following procedure outlines the method of decontaminating the instrument before packaging and shipment.

19.2. Purpose of Decontamination

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

19.3. General Considerations

Any laboratory instrument that has been used for clinical analysis is considered as a biohazard and should be decontaminated prior to handling. Intact surface is generally considered as an effective barrier against infectious organisms. However, small abraviations may not be always being visible. Gloves must be used incase the instrument is not decontaminated.

Mucous membranes are considered prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

Eating and drinking while decontaminating instruments is not advisable.

19.4. Procedure

A solution of 5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

Reassemble the unit and discard the used gloves and towels.

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20. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer: **Contact:**

Address: **Position:**

Tel:

Fax:

Model N°: **Serial N°:**

Accessoires Returned:

Purchase Date:

Reason for Complaint:

Has the equipment been exposed to any of the following;
(*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO
If YES, please specify

b) Other Biohazard *YES/NO
If YES, Please specify